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Administrative Conference
of the United States

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A GUIDE TO FEDERAL AGENCY RULEMAKING

2nd edition

Office of
the Chairman
1991

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Administrative Conference of the United States

The Administrative Conference of the United States was established by statute as an independent agency of the federal government in 1964. Its purpose is to promote improvements in the efficiency, adequacy, and fairness of procedures by which federal agencies conduct regulatory programs, administer grants and benefits, and perform related governmental functions.

To this end, the Conference conducts research and issues reports concerning various aspects of the administrative process and, when warranted, makes recommendations to the President, Congress, particular departments and agencies, and the judiciary concerning the need for procedural reforms. Implementation of Conference recommendations may be accomplished by direct action on the part of the affected agencies or through legislative changes.

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A GUIDE TO FEDERAL AGENCY RULEMAKING

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Office of
the Chairman
1991

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CHAIRMAN'S FOREWORD

The Administrative Procedure Act established a simple procedure for informal, as opposed to "formal,"[1] rulemaking. Agencies are required to publish a notice of proposed rulemaking that includes "either the terms or substance of the proposed rule or a description of the subjects and issues involved,"[2] and interested persons are to be given an "opportunity to participate in the rulemaking through submission of written data, views, or arguments."[3] The APA afforded agencies great latitude in deciding whether or not to employ additional procedures beyond bare notice and comment.

In the decade or two after the Administrative Procedure Act was enacted, licensing and rate-making proceedings, formal adjudications, as well as formal rulemaking dominated the administrative law landscape. These processes, however, proved to be too cumbersome for implementing the flood of new legislation passed in the late 1960's and early 1970's by which the government sought to remedy newly perceived health, safety and environmental problems. In a short time, informal rulemaking supplanted the APA's formal processes as the preferred means of formulating major governmental policies. Indeed, a leading commentator proclaimed such notice-and-comment procedures to be "one of the greatest inventions of modern government."[4]

The increasing use of informal rulemaking to resolve complex, high-stakes issues led by the mid- and late-1970's to new statutes and court decisions that placed additional procedural hurdles before agencies seeking to promulgate rules. In addition, the late 1970's and 1980's saw an increased presidential involvement in the development of regulatory policies. These developments are seen by one observer as having "taken the bloom off the rulemaking rose."[5]

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[1] Where "formal rulemaking" is required, the trial-type procedures of 5 U.S.C. §§ 556, 557, must be followed.

[2] 5 U.S.C. § 553(b).

[3] *Id.*, § 553(c).

[4] K. Davis, Administrative Law Treatise V. 1, 6.15 (Supp. 1970). See also *Present at the Creation: Regulatory Reform Before 1946*, 38 Admin. L. Rev. 511, 520 (1986) (Interview of K. Davis and W. Gellhorn by P. Verkuil).

[5] Scalia, *Back to Basics: Making Law Without Making Rules*, Regulation, July/Aug. 1981, at 25, 26.

Rulemaking's effectiveness for establishing standards and norms has been called into question,[6] and some have perceived an increase in agency use of "non-rule rulemaking," *i.e.*, the setting of standards through memoranda or guidelines intended to have the functional effect of rules.[7] Despite criticism, however, informal rulemaking continues to be central to the maintenance of the administrative state, and according to the Office of Management and Budget, over 5,000 final rule documents were published in the Federal Register in 1989.

Given the extensive use of rulemaking in federal agencies, it is important that agency rulemakers have available as clear guidance as possible. As procedures governing the rulemaking process have proliferated since the Administrative Procedure Act was enacted, the potential procedural pitfalls have multiplied. And while some agencies are immersed in the rulemaking process, other agencies only infrequently extend their toes into it.

This Guide to Federal Agency Rulemaking has been prepared to fulfill the Administrative Conference's function of encouraging the exchange of information among agencies. The Administrative Conference of the United States is an independent federal agency in the Executive Branch, established in 1968 as an advisory agency in administrative law and procedure. The Conference has broad authority to conduct studies and make recommendations for improving the efficiency, adequacy and fairness of the procedures agency use in carrying out their administrative programs and to collect data and publish reports useful for evaluating and improving administrative procedure.

The Conference is composed of the Chairman, the Council and the Assembly. The Chairman is appointed by the President and is the chief executive of the Conference. The Council is composed of the Chairman and ten members who serve as a "board of directors." The Assembly is comprised of approximately 100 members, consisting of representatives of federal agencies, boards and commissions and private citizens, including lawyers, law professors, and others knowledgeable about administrative law and practice. The Guide to Federal Agency Rulemaking is a publication of the Office of the Chairman, and does not necessarily represent the views of the Council or the Assembly, except as it references formal Administrative Conference Recommendations.

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[6] *See* Pierce, *Unruly Judicial Review of Rulemaking*, 5 Nat'l Resources & Env't 23 (Fall 1990)("In 1990, this ingenious device for policymaking [rulemaking] is in danger of being relegated to a chapter in a legal history book."); J. Mashaw & D. Harfst, The Struggle for Auto Safety (1990).

[7] *See* R. Anthony, Project on "Non-Rule Rulemaking" (Preliminary Outline to the Administrative Conference, December 1990).

This Guide pulls together into one publication a summary of all of the procedures that affect the rulemaking process, so that rulemakers in each federal agency will not have to "reinvent the wheel." It is intended especially for agencies and their staff members who are newcomers to the rulemaking field, although we hope that it is also useful to experienced rulemakers, rulemaking participants and teachers of administrative law. The first edition of this guide was sparked by my predecessor, Loren A. Smith, now Chief Judge of the United States Claims Court. I trust he will find this second edition agreeable with the goal to which he set the first: "that we all have as clear and as comprehensive an understanding as is possible of the process by which rules are made and tested."[8]

The demand for the original Guide far exceeded our expectations, and it has been largely unavailable, except in libraries, for several years. Further, like most areas of the law, the law relating to administrative agency rulemaking has not remained static. There have been numerous statutory changes and presidential oversight of the rulemaking process has increased. The courts have resolved some issues, while introducing ambiguities into others. We discuss some of these recent trends in this second edition.

I wish to acknowledge the valuable contribution to this edition of Professor Benjamin Mintz of Catholic University, who served as the consultant and whose insights are evident throughout its pages. I want to commend Nancy G. Miller of this Office for her effective and thorough assistance as project director. I would like, as well, to thank Michael W. Bowers, Deputy Research Director of the Administrative Conference, for his work on this edition as well as his contribution to the original Guide.

Marshall J. Breger
Chairman

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[8] Chairman's Foreword, A Guide to Federal Agency Rulemaking, p. ix (1983).

PREFACE

In 1983, the Administrative Conference of the United States published A Guide to Federal Agency Rulemaking. It was intended to (1) provide agency personnel responsible for conducting rulemaking proceedings with an integrated view of the many requirements that now apply to rulemaking; (2) publicize Conference studies and recommendations dealing with the subject of rulemaking; and (3) promote the interchange of information about agency rulemaking procedures. This second edition of the Guide, which updates the 1983 version, is intended to serve the same purposes. It has been prepared by the Office of the Chairman with the assistance of Professor Benjamin Mintz, who served as consultant. Professor Mintz is on the faculty of the Columbus School of Law, The Catholic University of America. He previously served as Assistant Solicitor for Occupational Safety and Health in the Department of Labor, and has previously been with the Department of Justice and the National Labor Relations Board.

The Guide has four Parts. Part I is an overview of federal agency rulemaking, and describes the major institutional "players" and historical development of rulemaking. Part II describes the statutory structure of rulemaking, including the relevant sections of the Administrative Procedure Act and other statutes that have an impact on present-day rulemaking. Part III contains a step-by-step description of the informal rulemaking process, from the preliminary considerations to the final rule. Part IV discusses judicial review of rulemaking. Appendices include some of the key rulemaking documents.

While the second edition has a slight shift in emphasis toward more discussion of court decisions in the area of informal rulemaking, the Guide is not intended to be a complete catalog of relevant cases, nor should it be considered the definitive word on their significance. Rather, it should be used as a starting point for discussion or further research on administrative law issues pertaining to agency rulemaking.

Although this Guide was not intended to be a complete overhaul of the original work, considerable updating has been required to address adequately significant rulemaking developments that have occurred since 1983. We would like to thank Professor Mintz for his willingness to assist the Conference in this major effort and for his valuable contribution as the consultant on this project. I would like especially to thank Michael Bowers, who was the project director on the original guide and who has provided invaluable assistance on the second edition. I would also like to thank the rest of the staff of the Office of the Chairman for their help, particularly Susan Mack and Karen Williams, who provided secretarial support. We would also like to thank those people in various federal agencies and elsewhere who reviewed drafts of the Guide and gave us their helpful comments.

Nancy G. Miller
Administrative Conference
of the United States
Project Director

FEDERAL AGENCY RULEMAKING

PART I: OVERVIEW OF FEDERAL AGENCY RULEMAKING

Passage of the Administrative Procedure Act (APA)[1] in 1946 established the basic framework of administrative law governing agency action, including rulemaking. While the provisions of the APA continue to be central to the rulemaking process, a number of developments have, to some extent, undermined the original unifying effect of the APA. Congress, beginning around 1970, enacted a variety of specific regulatory statutes that mandated rulemaking procedures to supplement or supersede the APA's provisions.[2] In addition, many administrative agencies significantly modified their rulemaking procedures in response to court-mandated refinements and the increasing complexity and controversial nature of many rulemakings.[3] A series of presidents have, by executive order, imposed procedural requirements on rulemaking by executive branch agencies that went beyond procedures required by the APA.[4] At the same time, a trend toward deregulation began in the late 1970's and continued throughout much of the administration of President Reagan.[5]

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[1] 5 U.S.C. §§ 551-59, 701-06, 1305, 3105, 3344, 5372, 7521. *See Administrative Law Symposium*, 72 Va. L. Rev. 215 (1986) (symposium on the history and contemporary impact of the APA, marking Act's fortieth anniversary).

[2] *See, e.g.*, Occupational Safety and Health Act, 29 U.S.C. § 651 *et seq.*; Consumer Product Safety Act, 15 U.S.C. § 2051 *et seq.*; Federal Trade Commission Improvement Act, 15 U.S.C. § 41 *et seq.*; Mine Safety and Health Act, 30 U.S.C. § 801 *et seq.* These statutes are often referred to as "hybrid" rulemaking statutes, since they combine elements of both "formal" and "informal" rulemaking. *See* Williams, *"Hybrid Rulemaking" Under the Administrative Procedure Act: A Legal and Empirical Analysis*, 42 U. Chi. L. Rev. 401 (1975). The term "hybrid rulemaking" was anticipated prior to publication of the Williams article. *See* Clagett, *Informal Action - Adjudication - Rulemaking: Some Recent Developments in Federal Administrative Law*, 1971 Duke L. J. 51, 70 (urging agencies to fashion "hybrid or conglomerate procedural devices"). "Hybrid" rulemaking is discussed *infra*, subs. (C).

One of this Guide's major purposes is to provide agency rulemakers, participants and others interested in agency rulemaking an integrated view of the procedural requirements as they relate to each stage of the rulemaking process. Before embarking on a stage-by-stage discussion, however, the major events in the development of the federal rulemaking process will be summarized.

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[3] The Supreme Court in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519, 524 (1978) (hereinafter *Vermont Yankee*), reaffirmed the principle that "[a]gencies are free to grant additional procedural rights [in rulemaking] in the exercise of their discretion . . . ."

[4] The most important of these is Executive Order No. 12,291, 3 C.F.R. 127 (1981 compilation), set out as note to 5 U.S.C. § 601, whose stated purpose is "to reduce the burdens of existing and future regulations, increase agency accountability for regulatory actions, provide for presidential oversight of the regulatory process, minimize duplication and conflict of regulations and insure well-reasoned regulations." Exec. Order No. 12,291 and other more recent executive orders governing agency rulemaking are discussed *infra*, subs. (D) and Part III, Ch. 2.

[5] An extensive literature has developed on the subject of deregulation and its impact on agency rulemaking. *See, e.g.*, S. Breyer, Regulation and Its Reform (1982); Garland, *Deregulation and Judicial Review*, 98 Harv. L. Rev. 507 (1985); McGarity, *Regulatory Reform in the Reagan Era*, 45 Md. L. Rev. 253 (1986); R. Litan & W. Nordhaus, Reforming Federal Regulation (1983); Rabin, *Federal Regulation in Historical Perspective*, 38 Stan. L. Rev. 1189, 1315-26 (1986); Smythe, *Judicial Review of Rule Rescissions*, 84 Colum. L. Rev. 1928 (1984).

Part I: Overview of Federal Agency Rulemaking

A. Rulemaking Under the Administrative Procedure Act

The APA was the product of a struggle between interests that supported the programs of the New Deal agencies and those that were afraid or suspicious of the power given those agencies.[6] One of the APA's major accomplishments was the establishment of minimum procedural requirements for many types of agency proceedings. However, the APA did not require -- as earlier bills would have -- that all administrative action follow a single, rigid procedural model.[7] Instead, the APA recognized and adopted various agency procedures that are commonly characterized as "formal adjudication," "formal rulemaking," "informal adjudication," and "informal rulemaking."

The emphasis in this Guide is on "informal" rather than "formal" rulemaking. Formal rulemaking is triggered only where a statute other than the APA requires a rule to "be made on the record after opportunity for an agency hearing."[8] Although formal rulemaking procedures are discussed below in Part II, Chapter 1, they will not be analyzed in detail in this Guide, since they are seldom used except in ratemaking and food additive cases and in other limited categories of proceedings.

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[6] *See* Verkuil, *The Emerging Concept of Administrative Procedure*, 78 Colum. L. Rev. 258, 268-74 (1978).

[7] The need for procedural variety and flexibility was shown by the excellent empirical research conducted by the Attorney General's Committee on Administrative Procedure, in existence from 1939-1941 and chaired by Dean Acheson. *See generally* Attorney General's Committee on Administrative Procedure, Final Report on Administrative Procedure in Government Agencies, S. Doc. No. 8, 77th Cong., 1st Sess. (1941).

[8] 5 U.S.C. § 553(c).

Section 553 of Title 5, United States Code, is the APA's general rulemaking section: rulemaking governed by it is commonly called "informal", "APA" or "notice-and-comment" rulemaking. The "notice-and-comment" label derives from the fact that section 553 requires: (1) publication of a notice of proposed rulemaking, (2) opportunity for public participation in the rulemaking by submission of written comments, and (3) publication of a final rule and accompanying statement of basis and purpose not less than 30 days before the rule's effective date. It is important to stress that these requirements are the procedural "floor" below which an agency may not go in prescribing procedures for a particular rulemaking. The APA's drafters contemplated that "[m]atters of great import, or those where the public submission of facts will be either useful to the agency or a protection to the public, should naturally be accorded more elaborate public procedures."[9]

As discussed below,[10] however, even the procedural "floor" set in section 553 does not apply to all rulemaking. Certain types of rules are exempted from some of these requirements, and entire classes of rules are totally exempted from APA notice-and-comment requirements. These exemptions reflect the APA drafters' cautious approach to imposing procedural requirements on a myriad of agency functions, as well as their willingness, in some situations, to permit agencies a measure of discretion in fashioning procedures appropriate to the particular rulemaking involved.

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[9] Senate Comm. on the Judiciary, Report on the Administrative Procedure Act, S. Rep. No. 752, 79th Cong., 1st Sess. 201 (1945).

[10] *See infra*, Part II, Ch. 1.

Congress' original willingness to leave to agency discretion rulemaking procedures exceeding the bare minimum required by section 553 partially eroded in the subsequent three decades. Federal courts, Congress, and the president have taken steps to require that agencies follow more rigorous procedures. More recently, however, these tendencies have slowed down, largely because rulemaking was becoming increasingly cumbersome and time-consuming, with the result that many of the benefits of "informal" rulemaking were being lost. The Supreme Court decision in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*[11] was a crucial event in preserving "informality" in informal rulemaking. These developments are discussed below in greater detail.

B. Agency Rulemaking and The Courts

The APA broadly grants to persons aggrieved or adversely affected by agency actions, including agency promulgation of rules, the right to seek judicial review of those actions.[12] Limited exceptions are provided: specifically, where another statute precludes judicial review or the action is committed to agency discretion.[13] Most statutes establishing regulatory programs provide for court review of agency rules.[14] Unless the enabling statute contains a controlling judicial review provision,[15] reviewing courts generally follow section 706 of the APA in determining the scope of court review. Because the standards are stated in general terms, and the application of particular standards of review to specific types of proceedings is not defined clearly by the APA, the judicial review provisions have been the subject of much court interpretation. A number of landmark Supreme Court decisions have been important in explicating the relationship between the courts and administrative agencies in the rulemaking area.

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[11] *Supra* n. 3.

[12] *See* 5 U.S.C. §§ 701-06. *See generally* Part IV, *infra*.

[13] *See* 5 U.S.C. § 701(a). The scope of these exceptions has been the subject of court decisions, particularly in the context of suits to compel agency action. *See* discussion *infra*, Part IV, Ch. 2, 3.

[14] *See* Part IV, Ch. 1.

The first of these decisions, *Citizens to Preserve Overton Park, Inc. v. Volpe,*[16] involved judicial review of the Secretary of Transportation's decision to authorize a road through a park. The Supreme Court first reaffirmed the presumptive reviewability of agency decisions, by narrowly construing the APA exceptions to the right to judicial review contained in section 701(a).[17] The Court then applied the "arbitrary and capricious" test of section 706(2)(A), concluding that it "must consider whether the [Secretary's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment."[18] The Supreme Court defined the reviewing court's obligation in the following language:

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[15] Thus, for example, the OSHA statute provides that OSHA's determination shall be upheld "if supported by substantial evidence in the record considered as a whole." 29 U.S.C. § 655 (f). The meaning of the "substantial evidence" test as applied to "informal" or "hybrid" rulemaking has been explicated in a number of court of appeals decisions. *See infra,* Part IV, Ch. 2.

[16] 401 U.S. 402 (1971).

[17] *Id.* at 410. On this issue, the Supreme Court relied on *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), holding that there must be "clear and convincing evidence" of a legislative intent to restrict judicial review.

[18] 401 U.S. at 416.

"Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency."[19] Finally, the Supreme Court, refusing to accept as a basis for the agency decision "post hoc" rationalizations contained in agency affidavits offered for purposes of litigation, stated that, in order to perform its review responsibilities, it must have before it "an administrative record that allows the full, prompt review of the Secretary's action . . . ."[20]

Overton Park has had a lasting impact on court review of rulemaking, even though the proceeding in that case was not rulemaking.[21] The courts continue to apply the presumption of reviewability of agency action,[22] and the Supreme Court's emphasis on the importance to the review process of the record has been extremely influential in the development of rulemaking procedures. The "searching and careful" standard of review described in the *Overton Park* decision, often called "hard look" review, has subsequently been applied by the courts to both substantive and procedural issues.[23]

The application of "hard look" review to procedural issues in rulemaking resulted in a series of "hybrid rulemaking" decisions by the courts of appeals, principally the District of

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[19] *Id.*

[20] *Id.* at 419. The Secretary of Transportation's determination was set aside and remanded to the district court for "plenary review." *Id.* at 419-20.

[21] The action, which involved approval of the building of a specific road, would more appropriately be characterized as "informal adjudication."

[22] *Cf. Heckler v. Chaney*, 470 U.S. 821 (1985), and related cases, discussed *infra*, Part IV, Ch. 3, on the issue of the reviewability of agency inaction.

[23] *See* Part IV, Ch. 2.

Columbia Circuit. These decisions mandated procedures in agency rulemaking that went beyond the minimum requirements of section 553.[24] Most of the early hybrid rulemaking judicial decisions involved rulemaking under statutes calling either for a decision after a hearing (but not on the record) or for "substantial evidence" review.[25] Although the courts refused to apply formal rulemaking procedures to these proceedings, they did remand final rules to the agencies for additional development of issues through cross-examination of witnesses or other unspecified procedural devices.[26]

In *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*,[27] the Supreme Court substantially halted the development of judge-made "common law" of rulemaking procedure. In criticizing the District of Columbia Circuit's experimentation with hybrid procedure, the Court stated that

> generally speaking [§ 553 of the APA] established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures. Agencies are free to grant additional procedural rights in the exercise of their discretion, but reviewing courts are

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[24] This development is traced in DeLong, *Informal Rulemaking and the Integration of Law and Policy*, 65 Va. L. Rev. 257, 267-72 (1979).

[25] Review of informal rulemaking under the APA is under an "arbitrary or capricious" standard. 5 U.S.C. § 706(1). For discussion of these standards of review, see *infra*, Part IV, Ch. 2.

[26] *See, e.g., Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974); *International Harvester v. Ruckelshaus*, 478 F.2d 615 (D.C. Cir. 1973). These and related cases are discussed in Wald, Verkuil, Rabkin, Cutler, & Susman (moderator), *The Contribution of the D.C. Circuit to Administrative Law*, 40 Admin. L. Rev. 507 (1988).

[27] *Supra* n. 3.

> generally not free to impose them if the agencies have not chosen to grant them.[28]

Although *Vermont Yankee* precludes the invalidation of rules solely because an agency failed to use specific procedures not required by section 553, the decision did not overrule or overturn all the law of informal rulemaking that had been developed by the lower courts. And it did not affect continuing strict court review of agency adherence to the procedural requirements in the APA or in agency regulations.[29]

The late 1970's and early 1980's witnessed a marked increase in federal deregulation.[30] Deregulation was effected by legislation,[31] through administrative actions, including amendment and repeal of rules, and in some cases through administrative inaction and delay.[32] In 1983, the Supreme Court, in *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.* (*State Farm*),[33] reversed a major deregulatory action by the Reagan Administration. The Court vacated the National Highway Traffic Safety Administration's rescission of a previously-issued rule requiring passive restraints (airbags and passive safety belts) in new automobiles. The Supreme Court first rejected the manufacturers' argument that rescission of a rule should be treated on review as a refusal to promulgate standards, to which a very deferential standard of court review had traditionally been applied.[34] Concluding that "the forces of change do not always or necessarily point in the direction of deregulation," the Court decided that the regulatory direction in which the agency chooses to move "does not alter the standard of judicial review established by law."[35]

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[28] *Id.* at 524 (footnote omitted).

[29] *See* discussion *infra*, Part IV, Ch. 2, of judicial review of agency procedures in issuing rules.

[30] For a discussion of deregulation, see sources cited at n. 5, *supra*.

[31] *E.g.*, Motor Carrier Act of 1980, Pub. L. No. 96-296, 94 Stat. 793 (*codified in* scattered sections of 49 U.S.C.); Airline Deregulation Act, Pub. L. No. 95-504, 92 Stat. 1705 (*codified in* scattered sections of 49 U.S.C.).

[32] OSHA's delay in issuing a field sanitation standard, which spanned several presidential administrations, is an example. *See Farm Worker Justice Fund v. Brock*, 811 F.2d 613 (D.C. Cir. 1987), *vacated as moot*, 817 F.2d 890 (1987) (court decision ordering OSHA to issue the standard vacated when OSHA issued the standard, 52 Fed. Reg. 16,050 (1987)).

[33] 463 U.S. 29 (1983).

Applying the "arbitrary and capricious" standard of review in *State Farm*, the Supreme Court asserted that the "agency must examine the relevant data and articulate a satisfactory explanation of its action, including a 'rational connection between the facts found and the choice made.'"[36] "Normally," the Court said, "an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference of view or the product of agency expertise."[37]

By insisting on taking a "hard look" at agency deregulatory decisions, and requiring rigorous justification for such actions, the Supreme Court limited the sweep of its earlier decision in *Vermont Yankee*. In *State Farm*, the Supreme Court expressly distinguished *Vermont Yankee*, saying that it was not imposing any "additional procedural requirements on an agency" but, rather, was requiring the agency to consider in its decisional process an available "technological alternative" -- the use of air bags only -- "within the ambit of the existing Standard."[38]

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[34] *Id.* at 41.

[35] *Id.* at 42.

[36] *Id.* at 43, quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962).

[37] *Id.*

In a decision handed down a year after *State Farm*, the Supreme Court, in *Chevron U.S.A. Inc. v. Natural Resources Defense Council* (*Chevron*),[39] upheld an Environmental Protection Agency (EPA) rule under the Clean Air Act[40] allowing states to treat all of the pollution-emitting devices within the same industrial grouping as though they were encased in a single "bubble". Having determined that Congress did not have a "specific intention" concerning the interpretive issue before the court, the Supreme Court decided that the only question on review was whether or not the administrative agency's view was a "reasonable one." For a unanimous court, Justice Stevens stated:

> Judges are not experts in the field, and are not part of either political branch of the Government. Courts must, in some cases, reconcile competing political interests, but not on the basis of the judges' personal policy preferences. In contrast, an agency to which Congress has delegated policymaking responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration's views of wise policy to inform its judgments. While agencies are not directly accountable to the people, the Chief Executive

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[38] *Id.* at 50-51. On remand, the Department of Transportation issued a new rule relating to passive restraints, 49 Fed. Reg. 28,962 (1984), which was upheld by the District of Columbia Circuit. *State Farm Mutual Auto. Insur. Co. v. Dole*, 802 F.2d 474 (D.C. Cir. 1986), *cert. denied*, 480 U.S. 951 (1987).

[39] 467 U.S. 837 (1984).

[40] 42 U.S.C. § 7502(b)(6).

> is, and it is entirely appropriate for this political branch of the Government to make such policy choices -- resolving the competing interests which Congress itself either inadvertently did not resolve, or intentionally left to be resolved by the agency charged with the administration of the statute in light of everyday realities.
>
> When a challenge to an agency construction of a statutory provision, fairly conceptualized, really centers on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail. In such a case, federal judges -- who have no constituency -- have a duty to respect legitimate policy choices made by those who do.[41]

In adopting this highly deferential approach to agency rulemaking action, the Supreme Court in *Chevron* did not attempt to distinguish the *State Farm* decision.[42]

Another Supreme Court decision that may be important to agencies in a period of deregulation is *Heckler v. Chaney*,[43] although its relevance to agency rulemaking is unclear and, perhaps, tenuous. In that case, various petitioners challenged a decision of the Food and Drug Administration (FDA) not to investigate, under the Federal Food, Drug and Cosmetic Act, the use by a state of lethal drugs to execute criminals. The Court upheld the FDA decision not to pursue the matter. In an opinion for a majority of the court, Justice Rehnquist stated that the presumption of reviewability of administrative agency action articulated in cases such as *Overton Park* did not apply to suits to force agency action. The Supreme Court concluded that decisions by agencies not to enforce or prosecute, whether by civil or criminal process, are "generally committed to an agency's absolute discretion." This "general unsuitability" for judicial review, the Court said, results largely from the fact that decisions not to enforce "often involve[] a complicated balancing of a number of factors which are particularly within [the agency's] expertise."[44]

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[41] 467 U.S. at 865-66.
[42] For further discussion of these cases, *see* Part IV, Ch. 2.
[43] 470 U.S. 821 (1985).

Although the Supreme Court expressly stated that it was not deciding the reviewability of agency decisions not to initiate rulemaking proceedings,[45] the decision has been cited by parties in challenges to agency decisions not to initiate, or failures to complete, rulemaking. Several courts of appeals have considered the relevance of *Heckler v. Chaney* to rulemaking and have determined that *Chaney* did not preclude court review. However, these and earlier decisions hold that the standard of review of agency inaction or decisions not to initiate rulemaking should be highly deferential.[46]

C. Agency Rulemaking and The Congress

Congress has a pervasive influence on agency rulemaking activities. In the first place, Congress grants the fundamental authority to an administrative agency to engage in policy-making through rulemaking. The enabling regulatory statute typically will, at least in general terms, define the scope of agency authority,[47] and describe any specific rulemaking procedures the agency must follow in addition to, or in lieu of, the minimum requirements of 5 U.S.C. § 553. In "hybrid" rulemaking statutes, Congress mandates additional rulemaking procedures, such as requirements for informal public hearings,[48] cross-examination of witnesses,[49] more extensive statements of justification for proposed and final rules,[50] and the application of the "substantial evidence" test, normally reserved for adjudication, to court review of agency rules.[51] The inclusion of these additional procedures, most of which occurred in the 1970's, reflected in part the influence of pre-*Vermont Yankee* court decisions and a congressional view that the APA procedures, standing alone, did not necessarily assure adequate public participation or accuracy in agency rulemaking decisions or provide an adequate basis for judicial review.

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[44] These include determining whether violations actually occured, whether the agency's resources should be spent on the particular case and how the case fits the agency's overall policies. *Id.* at 831. The other reasons for "unsuitability" mentioned by the court are: (1) in refusing to enforce, the agency is not exercising its "coercive" power, and (2) refusals to enforce are analogous to decisions by a prosecutor not to indict, which have long been considered as the "special province" of the executive branch. *Id.* at 831-35.

[45] *Id.* at 825 n. 2.

[46] These cases are discussed *infra*, Part IV, Ch. 3.

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[47] For example, in *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 109 S.Ct. 468 (1988), discussed *infra*, Part III, Ch. 7, the Supreme Court held that the Medicare Act, 42 U.S.C. § 1395x(v)(1)(A), did not authorize the Secretary of HHS to promulgate retroactive cost-limit rules. The Court said, *id.* at 471 : "It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."

[48] E.g., under the OSH Act, the agency is required to hold a public hearing if an interested person files written objections to a proposed rule and requests a public hearing "on such objections." 29 U.S.C. § 655(b)(3). *See* 29 C.F.R. § 1911.11(d).

[49] *E.g.*, Federal Trade Commission Act, 15 U.S.C. § 57a(c)(2)(B).

[50] *See, e.g.*, Consumer Product Safety Act, 15 U.S.C. § 2058(f)(3).

[51] OSH Act, 29 U.S.C. § 655(f); FTC Act, 15 U.S.C. § 57a(e)(3). The "substantial evidence" test as applied to informal or "hybrid" rulemaking has been widely discussed in court decisions. *See also* discussion *infra*, Part IV, Ch. 2.

Congress has also sought to control and expedite agency rulemaking by imposing statutory deadlines for completing rulemaking actions. Congress has been particularly concerned about agency delay and inaction in the public health and environment areas. Thus, for example, the Asbestos Hazard Emergency Response Act of 1986[52] required EPA to publish, for seven specific areas relating to asbestos-containing materials in school buildings, an advance notice of proposed rulemaking within 60 days of enactment, a proposed rule within 180 days, and final rules within 360 days.[53]

Many other agency statutes have included deadlines for agency rulemaking action.[54] Typically these statutory deadlines can be enforced only by court suits;[55] however, in some cases Congress has added so-called "hammers"[56] or other penalties if an agency fails to take timely action. An example of a statutory "hammer" is a provision in the 1984 amendments to the Resource Conservation and Recovery Act, which gave EPA a specified period of time in which to issue regulations; if at the end of that time it had not acted, the "hammer" would fall; *i.e.*, a congressionally-specified regulatory result would go into effect.[57]

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[52] Pub. L. No. 99-519, 100 Stat. 2979, 15 U.S.C. § 264 *et seq.* (amending Toxic Substances Control Act, 15 U.S.C. § 2601 *et seq.*).

[53] 15 U.S.C. § 2643(a).

[54] It has been estimated that Congress imposed about 600 deadlines in various environmental statutes between 1970 and 1983, and added 60 more in the Hazardous and Solid Waste Amendments of 1984. Abbott, *The Case Against Federal Statutory and Judicial Deadlines: A Cost-Benefit Appraisal*, 39 Admin. L. Rev. 171, 173 (1987). *See also* Abbott, *Case Studies in the Costs of Federal Statutory and Judicial Deadlines*, 39 Admin. L. Rev. 467 (1987).

[55] The issues of court enforcement of statutory deadlines, and, more generally, of suits to compel agency action, are discussed *infra*, Part IV, Ch.3.

[56] *See* Shapiro, *"Congress' New Direction in Administrative Law,"* 13 Admin. L. News, Spring 1988, 8 (American Bar Ass'n).

The Administrative Conference has questioned the value of statutory rulemaking deadlines,[58] as have a number of commentators.[59] Congress continues to impose these deadlines, however, and they often are an important factor in court litigation to force agencies to initiate or complete rulemaking activity.[60]

Congress also seeks to monitor agency rulemaking after its completion. Prior to 1983, Congress had incorporated "legislative veto" provisions into many statutes authorizing agency rules.[61] Such statutes typically provided for review of final agency rules by one or both Houses of Congress. In 1983, however, the Supreme Court held in *Immigration and Naturalization Service v. Chadha*[62] that a statutory provision authorizing a one-house veto of the suspension of a deportation order by the Attorney General violated the separation of powers doctrine and was therefore unconstitutional.[63] Subsequently the Supreme Court applied *Chadha* to two-house vetoes and to vetoes of rules issued by administrative agencies.[64] While some types of Congressional review of rules promulgated by administrative agencies, such as "report-and-wait" provisions, are constitutional,[65] the legislative veto in its classic sense no longer is an option for Congressional control of rulemaking.[66]

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[57] 42 U.S.C. § 6924(d)(1), (2). *See also* Department of Transportation appropriations act provision that would reduce the agency budget if a particular rulemaking deadline were not met. Continuing Appropriations, Fiscal Year 1988, Pub. L. No. 100-202, Title I, Department of Transportation, Office of the Secretary, Salaries and Expenses (Including Transfer of Funds), 101 Stat. 1329-358 to 359, *cited in* Eisner, Agency Delay in Informal Rulemaking, Report to Admin. Law Section of American Bar Association 46 n. 150 (1988).

[58] Recommendation No. 78-3, "Time Limits on Agency Actions," 1 C.F.R. § 305.78-3.

[59] *See, e.g.*, articles cited *supra*, n. 54.

[60] See cases discussed *infra*, Part IV, Ch. 3.

[61] An inventory of these statutes as of 1983 appears as an appendix to the dissenting opinion of Mr. Justice White in *INS v. Chadha*, 462 U.S. 919, 1003-13 (1983). The appendix lists 56 statutes with provisions authorizing post-promulgation congressional review.

[62] 462 U.S. 919 (1983).

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[63] The *Chadha* decision has been the subject of extensive discussion. *See, e.g.*, Elliot, *INS. v. Chadha: The Administrative Constitution, the Constitution and the Legislative Veto*, 1983 Sup. Ct. Rev. 125.

[64] *U.S. Senate v. FTC*, 463 U.S. 1216 (1983), *aff'g Consumers Union v. FTC*, 691 F.2d 575 (D.C. Cir. 1982) (holding unconstitutional FTC Improvements Act provision authorizing two-House veto of FTC rules); *Process Gas Consumers Group v. Consumers Energy Council of America*, 463 U.S. 1216 (1983), *aff'g Consumer Energy Council of America v. FERC*, 673 F.2d 425 (D.C. Cir. 1982). The court of appeals decisions both preceded *Chadha*; the Supreme Court's summary affirmances followed *Chadha*.

[65] *Alexandria v. United States*, 737 F.2d 1022 (Fed. Cir. 1984).

[66] *See* Note, *Fate of the Legislative Veto After Chadha*, 53 Geo. Wash. L. Rev. 168 (1984-85). The impact of *Chadha* on existing legislative veto provisions remains an issue. Congress has amended several statutes to delete unconstitutional legislative vetoes. In some cases, it has provided for use of a joint resolution passed by Congress and signed by the President (in effect, legislation) to overrule agency action. *See, e.g.*, amendments to the Federal Salary Act of 1967, 2 U.S.C. § 351 *et seq.* (1985 & 1988 Supp.). However, many statutes containing pre-*Chadha* legislative vetoes remain unchanged. The Supreme Court addressed the severability of such provisions in *Alaska Airlines v. Brock*, 480 U.S. 678, 107 S. Ct. 1476 (1987). Congress had delegated to the Secretary of Labor authority to promulgate rules implementing a program to assist employees dislocated as a result of commercial airline deregulation, subject to a one-house legislative veto. The Court described the standard as follows: "Unless it is evident that the Legislature would not have enacted those provisions which are within its power, independently of that which is not, the invalid part may be dropped if what is left is fully operative as a law." 107 S. Ct. at 1480. The Court concluded that Congress would have enacted the disputed provisions even without a legislative-veto provision, observing that while labor protection was an important feature of the Act, Congress paid little attention to

Absent the availability of a legislative veto, debate has centered on other available means for Congress to oversee agency rulemaking activity. Statutory requirements limiting agency rulemaking discretion, discussed above, continue to be an important method of Congressional control. Another is the exercise of congressional oversight authority, either by formal or by informal means.[67] Congressional committees frequently hold oversight hearings on rulemaking issues and, in some cases, file reports expressing strong views on agency performance on particular matters.[68]

Informal contacts between agency rulemakers and Members of Congress and Congressional staff in connection with rulemaking are also frequent.[69] In *Sierra Club v. Costle*,[70] the District of Columbia Circuit held that it was "entirely proper" for Congressional representatives vigorously to represent the interests of their constituents before administrative agencies engaged in policy rulemaking, so long as the representative does not "frustrate the intent of Congress as a whole as

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the legislative veto. *Id.* at 1484. *See also City of New Haven v. United States*, 809 F.2d 900 (D.C. Cir. 1987) (holding legislative veto provision non-severable).

[67] There is an extensive literature on congressional oversight activity. *See, e.g.*, W. J. Oleszek, Congressional Procedures and the Policy Process 263-82 (1988); R. D. Arnold, Congress and the Bureaucracy: A Theory of Influence (1979).

[68] *See, e.g.*, a 1984 House Commerce and Energy Committee subcommittee report's sharp criticism of EPA's decision not to regulate asbestos under the Toxic Substances Control Act. House Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 99th Cong., 1st Sess., Report on EPA's Asbestos Regulations: a Case Study on OMB Interference in Agency Rulemaking (Comm. Print 1985). EPA reversed its position and initiated a rulemaking. 51 Fed. Reg. 3738 (1986).

[69] *See, e.g.*, J. M. Berry, Feeding Hungry People - Rulemaking in the Food Stamp Program (1984).

[70] 657 F.2d 298 (D.C. Cir. 1981).

expressed in statute, nor undermine applicable rules of procedure."[71]

Congress also controls agency rulemaking procedure by enacting generic procedural statutes, such as the National Environmental Policy Act,[72] the Paperwork Reduction Act,[73] and the Regulatory Flexibility Act.[74] These statutes, which are designed to improve the quality of agency decisionmaking and to further policy goals set forth in the statutes, have had a significant impact on the rulemaking process.[75]

D. Agency Rulemaking and The President

Perhaps the most significant administrative law development during the last two decades has been increased presidential involvement in federal agency rulemaking. This presidential review has been the result of numerous executive orders,[76] as well as enactment of the Paperwork Reduction Act.[77]

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[71] *Id.* at 408-10. *See* discussion *infra*, Part III, Ch. 6.

[72] 42 U.S.C. §§ 4321-61.

[73] 44 U.S.C. §§ 3501-20.

[74] 5 U.S.C. §§ 601-12.

[75] These and other generic statutes are discussed *infra*, Part II, Ch. 3, and Part III, Ch. 2.

[76] Exec. Order No. 12,291, 3 C.F.R. 127 (1981 Compilation); Exec. Order No. 12,498, 3 C.F.R. 323 (1985 Compilation); Exec. Order No. 12,606, 3 C.F.R. 241 (1987 compilation); Exec. Order No. 12,612, 3 C.F.R. 252 (1987 compilation); Exec. Order No. 12,630, 3 C.F.R. 554 (1988 compilation). All these Executive Orders are reprinted in 5 U.S.C. § 601 note.

[77] 44 U.S.C. §§ 3501-20. The Paperwork Reduction Act superceded the Federal Reports Act of 1942, Pub. L. No. 77-831 (1942).

Part I: Overview of Federal Agency Rulemaking

1. *The Development of Presidential Review*

Presidential oversight of regulation is not a recent innovation. It has been in effect, in one form or another, since 1971,[78] and it accompanied a major expansion in the scope and complexity of federal regulation that occurred in the 1960s and 1970s, when a number of important social and environmental regulatory statutes were enacted.[79]

In June 1971, President Nixon established a "Quality of Life Review" program, under which all "significant" draft proposed and final rules were submitted to the Office of Management and Budget (OMB), which circulated them to other agencies for comment.[80] Agencies were required to submit a summary of their proposals, a description of the alternatives that had been considered, and a cost comparison of alternatives. In practice, this program applied to rules pertaining to environmental quality, consumer protection and occupational health and safety.

In 1974, President Ford issued an executive order requiring executive branch agencies to prepare an "inflation impact statement" for each "major" federal action.[81] The order empowered the Director of OMB to administer the program, with authority to delegate functions to other agencies, including the Council on Wage and Price Stability (COWPS).[82] Under the Inflation Impact Statement program, agencies were required to prepare an IIS for "major" rules[83] prior to publication of the notice of proposed rulemaking (NPRM), and then to forward a summary of the IIS to COWPS upon publication of the NPRM.[84] COWPS would review the IIS and, in its discretion, offer informal criticism of the proposal or participate in the public proceedings on the rule.[85]

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[78] The evolution of presidential supervision is described in Bruff, *Presidential Management of Agency Rulemaking*, 57 Geo. Wash. L. Rev. 533 (1989), *reprinted in* 1988 ACUS Recommendations & Reports 527.

[79] For an excellent history of government regulation, *see* Rabin, *Federal Regulation in Historical Perspective*, 38 Stan. L. Rev. 1189 (1986).

[80] *See* Agency Regulations, Standards and Guidelines Pertaining to Environmental Quality, Consumer Protection, Occupational and Public Health and Safety, Memorandum to Heads of Department and Agencies from George P. Schultz, Director, OMB (Oct. 5, 1971), *cited in* Pedersen, *Formal Records and Informal Rulemaking*, 85 Yale L.J. 38, 52 n. 61 (1975).

President Carter continued presidential review of agency rules by means of Executive Order No. 12,044, issued in 1978.[86] Under the order, agencies[87] were required to: (1) publish semi-annual agendas, describing and giving the legal basis for, any "significant" regulations under development by the agency; (2) establish procedures to identify "significant" rules, to evaluate their need, and to have the agency head assure that the "least burdensome of the acceptable alternatives" was proposed; and (3) prepare a "regulatory analysis" that examined the cost-effectiveness of alternative regulatory approaches for "major rules."

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[81] Exec. Order No. 11,821, 3 C.F.R. 203 (1975 compilation). When the Executive Order was later extended, the name "Inflation Impact Statement" (IIS) was replaced by "economic impact statement" to better reflect the required analysis, which could be characterized as a loose cost-benefit analysis. *See* OMB Circular No. A-107, § 4(d) (Jan. 28, 1975), *cited in* Note, *The Inflation Impact Statement Program: An Assessment of the First Two Years*, 26 Am. U. L. Rev. 1138, 1141 n. 28. (1977).

[82] *See* Note, *The Inflation Impact Statement Program: An Assessment of the First Two Years*, *id.* at 1140.

[83] Originally, agencies were left to develop their own criteria for determining what was a "major" proposal, subject to OMB approval; eventually COWPS adopted a list of suggested criteria that essentially defined "major" as entailing a cost of $100 million or more in one year, or $150 million or more in two years. *See* Note, *Regulatory Analyses and Judicial Review of Informal Rulemaking*, 91 Yale L.J. 739, 746 n. 51 (1982).

[84] Note, *The Inflation Impact Statement Program*, *supra* n. 81, at 1142.

[85] *Id.*

[86] 3 C.F.R. 152 (1978 compilation).

[87] The order applied to executive branch agencies, but not to independent agencies.

President Carter also established a Regulatory Analysis Review Group to review the regulatory analyses prepared for a limited number of proposed "major" rules and to submit comments on the proposed rules during the public comment period.[88] He created another rulemaking review body, the Regulatory Council, which was charged with coordinating agency rulemaking to avoid duplication of effort or conflicting policy in regulation of any area.[89] These efforts to coordinate agency rulemaking were challenged in several lawsuits.[90]

President Reagan acted quickly after taking office to increase control over executive branch rulemaking. On February 17, 1981, the President issued an executive order on federal regulations designed "to reduce the burdens of existing and future regulations, increase agency accountability for regulatory actions, provide for Presidential oversight of the regulatory process, minimize duplication and conflict of regulations, and insure well-reasoned regulations."[91] The new Executive Order No. 12,291 replaced Executive Order No. 12,044, which President Reagan said had "proven ineffective."[92]

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[88] 43 Fed. Reg. 12,668 (1978).

[89] Memorandum from President Carter to Executive Departments and Agencies, entitled "Strengthening Regulatory Management" (Oct. 13, 1978). The Regulatory Council included the heads of all executive branch agencies and the heads of any independent agencies who chose to participate on a voluntary basis.

[90] For accounts of the controversy, *see* Baram, *Cost-Benefit Analysis: An Inadequate Basis for Health, Safety, and Environmental Regulatory Decisionmaking*, 8 Ecology L.Q. 473, 512-14 (1980); Verkuil, *Jawboning Administrative Agencies: Ex Parte Contacts by the White House*, 80 Colum. L. Rev. 943, 944-47 (1980).

Executive Order No. 12,291 contains both substantive requirements for new rules and procedural steps to be followed in their development and promulgation.[93] The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget was given responsibility for implementing Executive Order No. 12,291. OMB's rulemaking review function is supplemented by the powers it was given in the Paperwork Reduction Act of 1980, by which Congress statutorily established OIRA to, among other things, review and approve or disapprove agency "information collection requests."[94]

The Office of Legal Counsel in the U.S. Department of Justice issued an opinion supporting the validity of Executive

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[91] Exec. Order No. 12,291, 3 C.F.R. 127 (1981 compilation), set out as a note to 5 U.S.C. § 601.

[92] Office of the Vice President, Fact Sheet Accompanying Executive Order On Regulatory Management, p. 2 (Feb. 17, 1981).

[93] The Order's requirements are discussed in Part III, Ch. 2(A), *infra*.

[94] 44 U.S.C. § 3501-20. It is important to note that OMB's power under the Paperwork Reduction Act extends to independent regulatory agencies in the executive branch. OMB has issued regulations setting forth procedures for clearance of informational requirements contained in agency rules, as well as procedures for collection requests not contained in rules. 5 C.F.R. Part 1320. *See* Part III, Ch. 2(B), *infra*.

Order No. 12,291.[95] The opinion stated that the President's authority to issue the order was based on his constitutional power to "take care that the laws be faithfully executed."[96] While concluding that any inquiry into Congressional intent in enacting specific rulemaking statutes "will usually support the legality of Presidential supervision of rulemaking by Executive Branch agencies,"[97] the opinion stated that Presidential supervision of agency rulemaking "is more readily justified when it does not purport wholly to displace, but only to guide and limit, discretion which Congress had allocated to a particular subordinate official."[98]

Despite criticism of this new form of presidential review,[99] President Reagan began his second term by expanding the program through Executive Order No. 12,498,[100] which established a "regulatory planning process" with the purpose of helping to "ensure that each major step in the process of rule development is consistent with Administration policy."[101]

According to OMB, the problem with regulatory review under Executive Order No. 12,291 was that such review "often came late in the regulatory process, after huge investments of agency time and resources, and often after agency staff commitments to constituents had made it extremely difficult to consider any legally acceptable, but previously ignored, regulatory alternative."[102] This resulted, OMB said, in the fact that the "bureaucracy often presented agency heads with *faits accompli*."[103]

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[95] Op. Office of Legal Counsel, Dep't of Justice, Proposed Executive Order entitled "Federal Regulation" (Feb. 18, 1981), *reprinted in* 1988-1989 *Regulatory Program of the United States Government* at 532-36.

[96] *Id.* at 532.

[97] *Id.* at 533.

[98] *Id.* at 533-34.

[99] *See* discussion in subs. (2), *infra.*

[100] *Supra* n. 76, *reprinted in* 5 U.S.C. § 601 note.

[101] OMB, 1987-1988 *Regulatory Program of the United States Government*, at xiv.

Executive Order No. 12,498's regulatory planning process was designed to avoid this problem.[104] Under this procedure, the head of each agency must determine at the beginning of the regulatory process whether a proposed regulatory venture is "consistent with the goals of the Administration."[105] Agency heads are to develop every year, at the beginning of the year, a plan for managing the agency's most significant regulatory actions. OMB then reviews the plan for consistency with the administration's program and publishes the coordinated agency plans in a government-wide document.[106] This document, entitled *Regulatory Program of the United States Government*, governing more than 20 major rulemaking agencies, is published each year to inform Congress and the public of the government's regulatory plans.[107]

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[102] *Id.* at xliii

[103] *Id.*

[104] President's Memorandum for the Heads of Executive Departments and Agencies, 21 Weekly Comp. Pres. Doc. 13 (1985).

[105] *Id.*

[106] Exec. Order No. 12,498, §§ 2, 3.

[107] The introduction to this document has provided detailed guidance to agencies in carrying out their regulatory programs in accordance with Administration policy. *See, eg.*, 1990-1991 *Regulatory Program of the United States Government*, at 3-41 ("Overview and Summary"). It should be noted that the *Regulatory Program of the United States Government* is completely separate from the Unified Agenda of Agency Regulations, issued under Executive Order No. 12,291 and the Regulatory Flexibility Act, even though some rules are covered in both documents. *See* discussion *infra*, Part III, Ch. 2.

President Reagan in 1987 and 1988 issued three additional executive orders, dealing with federalism,[108] interference with property rights,[109] and the family,[110] and OMB was given a role in ensuring coordination of regulatory policy in these areas.[111] President Bush has continued the program of presidential review of agency rulemaking established by President Reagan.

2. *The Policy Debate Over Presidential Review*

The policy arguments favoring presidential review of agency rulemaking include the following:

- The President is in a good position to "centralize and coordinate" the rulemaking process; this task has become particularly important with the proliferation of administrative agencies, whose responsibilities often overlap with one another;[112]

- Since the President is "electorally accountable," and is the "only official in government with a national constituency," he is "uniquely well-situated to design regulatory policy in a way that is responsive to the interest of the public as a whole";[113]

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[108] Exec. Order No. 12,612, 3 C.F.R. 252 (1987 compilation). The Order is designed to ensure that executive departments are guided by "principles of federalism," *see* 52 Fed. Reg. 41,685 (1987).

[109] Exec. Order No. 12,630, 3 C.F.R. 554 (1988 compilation). The Order relates to "Governmental Actions and Interference with Constitutionally Protected Property Rights," *see* 53 Fed. Reg. 8859 (1988).

[110] Exec. Order No. 12,606, 3 C.F.R. 241 (1987 compilation). The Order is designed to "ensure that the autonomy and rights of the family are considered" in the formulation of government policy, *see* 52 Fed. Reg. 34,188 (1987).

[111] *See* Part III, Ch. 2(D), for further discussion of these executive orders.

[112] Strauss & Sunstein, *The Role of the President and OMB in Informal Rulemaking*, 38 Admin. L. Rev. 181, 189 (1986) [hereafter Strauss & Sunstein].

- By virtue of his "accountability and capacity for centralization," the President is able "to energize and direct regulatory policy," which is especially important when there is a national consensus that regulatory policy "be moved in particular directions";[114]

- Presidential supervision, particularly as embodied in Executive Order No. 12,498, enables an agency head to focus at an early stage on the agency regulatory program and thus to better control agency staff and the planning process.[115]

On the other hand, presidential review of agency rulemaking, as implemented through OMB, has been criticized by members of Congress, public interest groups, and commentators. These criticisms are variously based on constitutional, statutory, and management principles.

- *Violation of constitutional separation of powers.* Among the objections raised to the presidential review process is that OMB violates constitutional separation of powers when it seeks to "control" agency rulemaking authority that has been assigned to the agency by Congress in the enabling statute establishing the regulatory program.[116]

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[113] *Id.* at 190.

[114] *Id.* at 188-90. *See also* Bruff, *supra* n. 78, 57 Geo. Wash. L. Rev. at 540-46. This latter article is based on a report to the Administrative Conference of the United States, *see* 1988 ACUS Recommendations & Reports 527. Professor Bruff emphasizes two major roles to be served by presidential oversight: "coordinating policy on a national scale," and "conform[ing] individual rules to a set of general principles." He notes that while the President has the "unique capacity" to provide the necessary coordination, Congress is not "well-suited" to coordinate policy. *Id.*

[115] *See* Strauss & Sunstein, *supra* n. 112, at 187-88; Bruff, *supra* n. 78, at 551.

Other commentators disagree with this view, or at least are willing to accept the "facial legality" of the requirements of Executive Orders Nos. 12,291 and 12,498,[117] while recognizing that the administration of the presidential supervisory program has the "potential to transgress substantive or procedural substantive limits."[118]

- *Application to independent regulatory agencies.* Although the Department of Justice opined that presidential supervision of rulemaking could constitutionally be applied, within appropriate limits, to independent administrative agencies,[119] Executive Order No. 12,291 expressly exempts these agencies from its scope.[120] The President's authority to extend the executive order's requirements to independent agencies has been the subject of lively debate by legal commentators.[121] In a 1988 Recommendation, the Administrative Conference considered this issue and concluded that *as a matter of principle*, presidential review of rulemaking should apply to independent agencies to the same extent it applies to rulemaking of other executive departments and agencies.[122]

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[116] *See, e.g.*, Rosenberg, *Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12,291*, 80 Mich. L. Rev. 193 (1981).

[117] Strauss & Sunstein, *supra* n. 112, at 201.

[118] Bruff, *supra* n. 78, at 562; National Academy of Public Administration, Presidential Management of Rulemaking in Regulatory Agencies 8 (1987). Some critics argue that even if Presidential oversight may be justified on a theoretical basis, the current program has been implemented almost exclusively to achieve deregulatory goals, in contravention of enabling statutes. *See* McGarity, *Presidential Control of Regulatory Agency Decisionmaking*, 36 Am. U. L. Rev. 443, 454-62 (1987).

[119] *See* Bruff, *supra* n. 78, at 590 n. 338 and accompanying text.

[120] Exec. Order No. 12,291, ¶ 1(d) (definition of agency). Although President Reagan asked for voluntary compliance of independent agencies, the request was generally rejected. *See* Strauss & Sunstein, *supra* n. 112 at 202-03.

- *The effect of presidential review on the APA's public participation procedures.* Another frequently raised criticism of presidential review of agency rulemaking is the impact of that supervision on the rulemaking procedures prescribed by Congress in the Administrative Procedure Act. The argument has been made that nonpublic communications between OMB and the rulemaking agency during review of an agency rule deny members of the public an opportunity to rebut OMB's arguments made to the agency, and thus undermine the integrity of the rulemaking record.[123] However, despite an early court of appeals case to the contrary,[124] the courts generally have recognized that the APA does not bar "ex parte" or "off-the-record" contacts in informal rulemaking.[125]

Nevertheless, congressional and public pressure has been exerted on OMB to disclose at least some of its communications with agencies during rule review. OMB has responded to this pressure by implementing procedures for disclosure, contained in internal directives to OMB staff, which are discussed in Part III, Chapter 6.

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[121] *See* McGarity, *supra* n. 118; Strauss & Sunstein, *supra* n. 112, at 202-05. Bruff, *supra* n. 78, at 590-93.

[122] *See* subs. (D)(4), *infra*.

[123] *See, e.g.*, McGarity, *supra* n. 118, at 457-60; Olson, *The Quiet Shift of Power: Office of Management & Budget Supervision of Environmental Protection Agency Rulemaking Under Executive Order 12,291*, 4 Va. J. Nat. Resources 1, 75-77 (1984).

[124] *See Home Box Office v. FCC*, 567 F.2d 9 (D.C. Cir.), *cert. denied*, 434 U.S. 829 (1977).

[125] *See* Part III, Ch. 6, *infra*, for a discussion of this issue.

- *Delay of rulemaking.* Another objection to presidential review is that it has resulted in delays in completing the rulemaking process.[126] Executive Order No. 12,291 contains no deadlines for completing the review process, although it does exempt rules where review would "conflict with deadlines imposed by statute or by judicial order."[127]

OMB's Annual Report for 1989 on Implementation of Executive Order No. 12,291[128] compares OMB's review time for rules during the period 1981-89.[129] It shows that in 1981, the average review time for major rules was 13 days; for non-major rules it was nine days. In 1989, average review times were respectively 59 days and 28 days.[130]

The Administrative Conference's 1988 recommendation on presidential review of rulemaking addresses this issue, stating that such review should be completed in a "timely fashion" with due regard to statutory and other deadlines.[131]

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[126] *See* Bruff, *supra* n. 78, at 565-67; NAPA Report, *supra* n. 118, at 7, 37.

[127] Exec. Order No. 12,291 ¶ 8(a)(2). In *Environmental Defense Fund v. Thomas*, 627 F. Supp. 566 (D.D.C. 1986), the court ruled that OMB must complete its review in a timely fashion to allow the agency to meet statutory deadlines.

[128] *Reprinted in* 1990-1991 *Regulatory Program of the United States Government* at 623-52.

[129] *Id.* at 634 and Exhibit 12.

[130] *Id. See also* GAO, Regulatory Review, Information on OMB's Review Process, GAO/GGD-89-101FS (July 1989), App. V, Tables V.1, V.2.

[131] *See* n. 153, *infra*.

3. Judicial Reaction to Presidential Review

The District of Columbia Circuit's opinion in *Sierra Club v. Costle*,[132] a case concerning presidential involvement in EPA rulemaking during the Carter Administration, is often quoted as being supportive of the policy underlying presidential review. The opinion, authored by Judge Patricia Wald, states:

> The court recognizes the basic need of the President and his White House staff to monitor the consistency of executive agency regulations with Administration policy. He and his White House advisers surely must be briefed fully and frequently about rules in the making, and their contributions to policymaking considered. The executive power under our Constitution, after all, is not shared--it rests exclusively with the President. The idea of a "plural executive," or a President with a council of state, was considered and rejected by the Constitutional Convention. Instead the Founders chose to risk the potential for tyranny inherent in placing power in one person, in order to gain the advantages of accountability fixed on a single source. To ensure the President's control and supervision over the Executive Branch, the Constitution -- and its judicial gloss -- vests him with the powers of appointment and removal, the power to demand written opinions from executive officers, and the right to invoke executive privilege to protect consultative privacy. In the particular case of EPA, Presidential authority is clear since it has never been considered an "independent agency," but always part of the Executive Branch.
>
> The authority of the President to control and supervise executive policymaking is derived from the Constitution; the desirability of such control is demonstrable from the practical realities of

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[132] 657 F.2d 298 (D.C. Cir. 1981), discussed *supra*, subs. (C).

> administrative rulemaking. Regulations such as those involved here demand a careful weighing of cost, environmental, and energy considerations. They also have broad implications for national economic policy. Our form of government simply could not function effectively or rationally if key executive policymakers were isolated from each other and from the Chief Executive. Single mission agencies do not always have the answers to complex regulatory problems. An overworked administrator exposed on a 24-hour basis to a dedicated but zealous staff needs to know the arguments and ideas of policymakers in other agencies as well as in the White House.[133]

Sierra Club involved the propriety of nonpublic executive communications in an EPA rulemaking, and did not directly address the constitutionality of presidential review. To the present, no court has squarely addressed the constitutionality of the review program under Executive Order No. 12,291.

The constitutional issue was raised in *Public Citizen Health Research Group v. Tyson*,[134] where the petitioning public interest group asserted the invalidity of a portion of OSHA's ethylene oxide standard, in part on the ground that an important provision in the draft standard had been deleted by OSHA at OMB's direction, thus violating separation of powers principles.[135] The District of Columbia Circuit, however, reversed OSHA's decision on other grounds without deciding the separation of powers issue.[136]

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[133] *Id.* at 405-06 (footnotes omitted).

[134] 796 F.2d 1479 (D.C. Cir. 1986).

[135] The challenge by petitioner Public Citizen was supported in an *amicus* brief filed by the chairpersons of several committees of the House of Representatives.

[136] *Id.* at 1507.

In 1989, the Fifth Circuit, in *National Grain and Feed Association v. OSHA*,[137] rejected challenges to OSHA's decisionmaking process for issuing a grain handling standard, while remanding the rule on other grounds.[138] The court, however, first concluded that the record "belie[d]" the unions' contention that "behind-the-scenes" review by OMB under Executive Order No. 12,291 had displaced the Secretary's statutory role in formulating the OSHA standard.[139] The court also rejected the argument that judicial review had been obstructed by the "alleged off-the-record coercion of OSHA," saying that the "agency's final rule must stand or fall on the basis of the record before the agency, not on the basis of some 'secret record' of OMB's."[140]

In *Environmental Defense Fund v. Thomas*,[141] a case involving EPA rules, the District Court for the District of Columbia concluded that OMB, "by insisting on certain substantive changes,"[142] significantly delayed publication of proposed rules, thus causing EPA to miss a statutory deadline for promulgating regulations. The court set a new deadline for the final rule, and declared that OMB had no authority under Executive Order No. 12,291 to delay promulgation of EPA regulations beyond the date of a statutory deadline.[143]

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[137] 866 F.2d 717 (5th Cir. 1989).

[138] *Id.* at 729 n. 22.

[139] *Id.*

[140] *Id.* This argument, that the court looks to the record in reviewing the standard and that ex parte contacts are therefore not prejudicial, was also discussed by the court in *Sierra Club v. Costle*, *supra* n. 132, 657 F.2d at 407-08 .

[141] 627 F. Supp. 566 (D.D.C. 1986).

[142] *Id.* at 570.

[143] *Id.* at 570-72. For a debate on the issue of the legality of OMB review, *see* Morrison, *OMB Interference with Agency*

4. *The Administrative Conference's Position on Presidential Review*

In late 1988, the Administrative Conference considered the issue of presidential review of rulemaking, and adopted Recommendation No. 88-9, "Presidential Review of Agency Rulemaking."[144] The Conference stated that there had been sufficient experience under executive orders establishing presidential review of rulemaking to "warrant continuing such review with certain guidelines as to its implementation."[145] In making its Recommendation, the Administrative Conference assumed that the President has authority "to enunciate principles to guide agency rulemaking" even where the programmatic responsibilities have been delegated by statute to agencies.[146] The Conference emphasized, however, that presidential review, as the term was used in its Recommendation, "does not displace responsibilities placed in

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Rulemaking: The Wrong Way to Write a Regulation, 99 Harv. L. Rev. 1059 (1986); De Muth & Ginsburg, *White House Review of Agency Rulemaking*, 99 Harv. L. Rev. 1075 (1986). (Mr. Morrison is counsel for Public Citizen Litigation Group and Mr. De Muth and Judge Ginsburg are former OMB officials.)

[144] 1 C.F.R. § 305.88-9. The Recommendation defines "presidential review" as a "program of systematic executive oversight and dialogue that involves coordinating agency actions where conflicts exist, and in all cases probing the agency's fact and policy judgments, with the purpose of ensuring that the agency considers factors of importance to the President's policies to the extent permitted by law." *Id.* n. 3. This review, the Recommendation notes, "does not displace responsibilities placed in the agency by law," nor does it authorize considering factors not otherwise permitted by law. *Id.*

[145] *Id.*, Preamble. *See also* Bruff, *supra* n.78 (report of the Conference's consultant).

[146] Recommendation No. 88-9, Preamble.

the agency by law nor authorize the use of factors not otherwise permitted by law."[147]

The Administrative Conference concluded that presidential review "can improve the coordination of agency actions and resolve conflicts among agency rules and assist in the implementation of neutral priorities" and that it should apply generally to federal rulemaking.[148] Thus, the Conference concluded that "[a]s a matter of principle, presidential review of rulemaking should apply to independent regulatory agencies to the same extent it applies to rulemaking of Executive Branch departments and other agencies."[149]

The Conference recommended public disclosure of proposed and final agency rules submitted to OMB under Executive Order No. 12,291, final agendas and other schedules submitted to OMB under Executive Order No. 12,498, official written policy guidance from OMB,[150] communications from OMB containing factual information relating to the substance of the rulemaking, and "conduit" communications (*i.e.*, communications containing the views, positions, or information from persons outside the government).[151] The Recommendation also suggests procedures to be followed by OMB reviewing officials to discourage such "conduit" communications.[152]

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[147] *Id.*

[148] *Id.*, ¶ 1. The Recommendation, however, excluded formal rulemaking and rulemaking that resolves conflicting private claims to a valuable privilege.

[149] Recommendation 88-9, ¶ 2. The National Academy of Public Administration also recommended that, as a matter of policy, Congress should consider extending presidential review to independent regulatory agencies on an agency-by-agency basis. NAPA Report, *supra* n. 118, at 23.

[150] 1 C.F.R. § 305.88-9, ¶ 4. This disclosure would take place, the Recommendation states, when the relevant proposed or final rule or agenda is published. *Id.* The Recommendation notes that the provision applicable to written policy guidance modifies the Conference's earlier position in 1 C.F.R. § 305.80-6, ¶ 1, that agencies should be free to receive written or oral policy advice and recommendations from the President or his advisors "without having a duty to place these intragovernmental communications in the public file . . . ."

Finally, the Recommendation states that Presidential review "should be completed in a timely fashion" by both the reviewing office and the agencies, "with due regard for statutory and other relevant deadlines,"[153] but a specific time limit on review was not recommended.

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[151] These documents would be placed in the record "promptly." 1 C.F.R. § 305.88-9, ¶¶ 4, 5.

[152] *Id.*, ¶ 6. *See also* discussion Part III, Ch. 6(C)(1), *infra*.

[153] *Id.*, ¶ 3. While the Conference did not adopt a specific period for completion of review, the American Bar Association subsequently adopted a resolution urging OMB to complete review within 60 days. American Bar Association Resolution (Feb. 12-13, 1990). The ABA also endorsed Recommendation No. 88-9 in its entirety. Report No. 302, Reports with Recommendations, 1990 ABA Annual Meeting, Chicago, IL, Aug. 7-8, 1990.

FEDERAL AGENCY RULEMAKING

PART II: THE STATUTORY FRAMEWORK FOR RULEMAKING

This Part presents a general review of the procedural requirements imposed on agencies by the Administrative Procedure Act and by other generic procedural statutes. Chapter 1 describes the Administrative Procedure Act's requirements for informal rulemaking under 5 U.S.C. § 553 and for formal rulemaking following the procedures in 5 U.S.C. §§ 556 and 557. Chapter 2 compares the use of agency adjudication and rulemaking for policymaking. Chapter 3 discusses other government-wide procedural statutes that may affect agency rulemaking.

Part III, which follows this part, looks at the specific steps in the dominant form of agency rulemaking, informal or "notice-and-comment" rulemaking.

CHAPTER 1

THE ADMINISTRATIVE PROCEDURE ACT

The first question a person interested in agency rulemaking under the APA needs to consider is what is meant by "rulemaking" and what is a "rule". The next question is what type of rule the agency is developing. Different procedures apply to different kinds of rules. This guide primarily addresses "informal" or "notice-and-comment" rulemaking, but it is important initially to know whether notice-and-comment procedure or some other procedure is required by law for the particular rulemaking the agency is considering. In some cases, an agency is permitted to issue a rule without offering any opportunity for public participation.

This chapter will start by discussing what is a "rule" under the APA. It then will briefly discuss formal rulemaking, followed by a summary of the informal rulemaking provisions of the APA. The last section will discuss the exemptions from the APA rulemaking requirements.

A. "Rules" and "Rulemaking" Under the APA

In ordinary usage, a "rule" is a "prescribed guide for conduct or action."[1] However, an agency rulemaking official, trying to decide which procedure to follow in a rulemaking, must know the legal definition of "rule". For this, the first place to look is the Administrative Procedure Act, which defines "rule" as--

> the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing.[2]

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[1] Webster's Ninth New Collegiate Dictionary 1012 (1983).
[2] 5 U.S.C. § 551(4).

"Rule making" is defined in the APA as the "agency process for formulating, amending, or repealing a rule."[3]

Standing alone, the APA's definition of "rule" may not be too helpful. For example, an agency order directing Company X to cease and desist from engaging in a certain unlawful practice would fall within the literal terms of this definition. Yet, it is reasonably clear under the APA that a proceeding leading to the issuance of a cease-and-desist order ordinarily is adjudication and not rulemaking.[4]

The definition of "adjudication" sheds little additional light, for "adjudication" is defined as the agency process for formulating an "order"[5] and "order" is defined as "a final disposition whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing."[6] Thus, the APA's definitional structure is largely circular, since the definition of adjudication is residual.

To understand the thrust of the APA's distinction between rulemaking and adjudication, one must turn to the discussion in the Attorney General's Manual on the APA:

> [T]he entire Act is based upon a dichotomy between rule making and adjudication. Examination of the legislative history of the definitions and of the differences in the required procedures for rule making and for adjudication discloses highly practical concepts of rule making and adjudication. Rule making is

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[3] 5 U.S.C. § 551(5).

[4] *See* Attorney General's Manual on the Administrative Procedure Act (hereafter Attorney General's Manual) 15 (1947), *reprinted in* ACUS Federal Administrative Procedure Sourcebook (Office of the Chairman).

[5] 5 U.S.C. § 551(7).

[6] 5 U.S.C. § 551(6).

> agency action which regulates the future conduct of either groups of persons or a single person; it is essentially legislative in nature, not only because it operates in the future but also because it is primarily concerned with policy considerations. The object of the rule making proceeding is the implementation or prescription of law or policy for the future, rather than the evaluation of a respondent's past conduct. Typically, the issues relate not to the evidentiary facts, as to which the veracity and demeanor of witnesses would often be important, but rather to the policy-making conclusions to be drawn from the facts . . . . Conversely, adjudication is concerned with the determination of past and present rights and liabilities. Normally, there is involved a decision as to whether past conduct was unlawful, so that the proceeding is characterized by an accusatory flavor and may result in disciplinary action. Or, it may involve the determination of a person's right to benefits under existing law so that the issues relate to whether he is within the established category of persons entitled such benefits. In such proceedings, the issues of fact are often sharply controverted.[7]

Given the breadth of the definitions of "rulemaking" and "adjudication" in the APA, it is not surprising that some confusion exists with respect to the proper classification of certain agency proceedings.

The inclusion of agency statements of "particular applicability" in the APA's definition of "rule" probably creates the most difficulty, for most people think of rules as addressed to general situations and adjudication as addressed to particular situations. While it is true that the great majority of rules have some general application, and adjudication is nearly always particularized in its immediate application, the drafters of the APA wished certain actions of a particular nature, such as the setting of future rates or the approval of corporate reorganizations, to be carried out under the relatively flexible procedures governing rulemaking. Consequently, the words "or particular" were included in the definition.[8]

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[7] Attorney General's Manual, *supra* n. 4, at 14-15 (citations omitted). For a recent comparison of rulemaking and adjudication, see concurring opinion of Justice Scalia in *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 109 S.Ct. 468, 475 (1988). *See also* Ch. 2, *infra*.

Courts have upheld classification of agency action as a "rule" even though it applied to the activities of a single entity.[9] Probably no great change would occur if the words "or particular" were deleted from the definition of rule in section 551 of the APA. It is noteworthy that Executive Order No. 12,291's definition of "regulation or rule" does not include those words.[10]

In addition to classifying agency action as either rulemaking or adjudication, agencies must determine what type of rule they are developing, since different procedural requirements apply to different types of rules. The task of classification is complicated by the great variety of agency actions. Professor Kenneth Culp Davis has observed:

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[8] For discussion of the inclusion of "or particular" in the definition, *see* 2 K. Davis, Administrative Law Treatise § 7:3 (2d ed. 1978); Morgan, *Toward a Revised Strategy for Ratemaking*, 78 U. Ill. L. F. 21, 50 n. 143 (1978).

In 1970, the American Bar Association recommended revising the definition of "rule" to delete the words "or particular." The Administrative Conference endorsed the ABA proposal with the understanding that "[a] matter may be considered of 'general applicability' even though it is directly applicable to a class which consists of only one or a few persons if the class is open in the sense that in the future the number of members of the class may be increased." Statement of the Administrative Conference on ABA Resolution No. 1 Proposing to Amend the Definition of "Rule" in the Administrative Procedure Act, 1 C.F.R. § 310.2.

[9] *See, e.g., Hercules Inc. v. EPA*, 598 F.2d 91, 118 (D.C. Cir. 1978).

[10] Exec. Order No. 12,291, § 1(a), set out as a note to 5 U.S.C. § 601.

> Agencies issue rules, sub-rules, and sub-sub-rules, seemingly ad infinitum. What agencies denominate "rules" or "regulations" are usually readily recognizable as such, but other statements or announcements that are somewhat in the nature of rules are troublesome and are causes of confusion. Like courts, agencies make "rules" by generalizing in adjudicatory opinions; like courts, they legislate in the process of deciding individual cases. Furthermore, agencies' informal adjudication may be quite voluminous and may be largely recorded, and the products may be rulings, interpretations, staff letters, press releases, official speeches, and many other kinds of announcements. Some agencies have nothing but respectable vertebrates; others have inferior animals and crawling creatures that no one can classify as fish, fowl, or insect.
>
> Yet the problem of classification must be taken seriously, because often the required procedure, as well as the degree of authoritative weight, depends on it.[11]

Determining whether an agency action is a "rule" is often vexing, and has been the subject of much litigation. Two such cases are *Department of Labor v. Kast Metals Corp.*,[12] and *Industrial Safety Equipment Association, Inc. v. EPA.*[13] In *Kast Metals*, the issue was whether the Occupational Safety and Health Administration (OSHA) administrative plan for determining workplace inspection priorities was a "rule." Since it was conceded that the agency action was not adjudication, the priority plan, if not a rule, would be exempt from the notice-and-comment requirements or other procedural requirements of the APA.[14] The government, relying on the distinction between an "investigation" and "rulemaking," claimed that the inspection plan was "investigative" rather than "prescriptive" because the plan itself "does not require any action on the part of those regulated."[15] In rejecting this argument, the District of Columbia Circuit stated that the characterization of agency action is a function not of formal definitions but of the "intrinsic nature of the action in terms of the way of the agency does business."[16] The court concluded that the procedure by means of which the determination to investigate was made was separate from the investigation itself and the basis for this determination must be classified as a "rule" under the APA.[17]

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[11] 2 K. Davis, Administrative Law Treatise § 7:4 (2d Ed. 1978) 15.

[12] 744 F.2d 1145 (5th Cir. 1984).

[13] 837 F.2d 1115 (D.C. Cir 1988).

On the other hand, in *Industrial Safety Equipment Association, Inc. v. EPA*,[18] the District of Columbia Circuit held that a "Guide" issued by EPA and the National Institute for Occupational Safety and Health recommending the use of only two types of respirators as ideal models for protection against asbestos exposure but not as a regimen presently mandated under a mandatory occupational health standard, was not a "rule" under the APA.[19] Finding that Congress did not intend that the APA definition of "rule" be "construed so broadly" that every agency action would be subject to judicial review, the court emphasized the "advisory character" of the guide. Thus, the court concluded, the Guide "does not change any law or official policy presently in effect," nor narrow the basis of EPA legal certification of respirators, and therefore did not constitute a rule.[20]

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[14] 744 F.2d at 1149-51.

[15] *Id.* at 1149-50. This distinction was articulated in *United States v. W. H. Hodges & Co.*, 533 F.2d 276, 278 (5th Cir. 1976) (per curiam).

[16] 744 F.2d at 1150.

[17] *Id.* The court further held that even if classified as "investigative activity," the language of the OSHA Act, read together with the APA, "strongly suggests" that the plan should be classified as a rule. *Id.* at 1151. The court separately considered whether the agency action would be exempt from notice-and-comment requirements as a "procedural" rule. *Id.* at 1151-56. The court decided that the plan was exempt from notice and comment and therefore valid on this basis. *Id.* at 1156.

[18] *Supra* n. 13.

B. Formal Rulemaking Under the APA

Section 553 is the APA's informal rulemaking section, and it sets forth the notice-and-comment requirements that apply to most "legislative" rulemaking. However, the last sentence of section 553(c) states:

> When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

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[19] The particular issue before the court was whether the guide constituted "agency action" subject to review under the APA. *See* 5 U.S.C. §§ 702, 704. Since the APA defines "agency action" as "the whole or a part of an agency rule," 5 U.S.C. § 551 (13), the court confronted the question whether the guide was a "rule" under the APA. 837 F.2d at 1117, 1120.

[20] 837 F.2d at 1119-21. *Cf. San Diego Air Sports Center, Inc. v. FAA*, 887 F.2d 966 (9th Cir. 1989)(FAA letter to sport parachuting center that parachute jumping was no longer allowed in area, was "rule" for review purposes; since letter prohibited "*all* parachuting by any party . . . from the time it issued," it "clearly promulgates a rule.") *See also Thomas v. New York*, 802 F.2d 1443 (D.C. Cir. 1986), *cert. denied*, 482 U.S. 919 (1987).

That sentence establishes the distinction between informal or notice-and-comment rulemaking under section 553, and formal or "on-the-record" rulemaking under sections 556 and 557.

Sections 556 and 557 include requirements that the agency support its rule with substantial evidence in an exclusive rulemaking record;[21] that there be an oral hearing presided over by agency members or an administrative law judge;[22] that the parties be permitted to conduct such cross-examination "as may be required for a full and true disclosure of the facts;"[23] that there be no ex parte communication with the decisionmaker,[24] and that parties be allowed to submit proposed findings and conclusions and present exceptions to the initial or recommended decisions of subordinate agency employees or to tentative agency decisions.[25] Thus, formal rulemaking procedure is a trial-type procedure, even though not all of the APA's procedures for formal adjudication apply to such rulemaking.[26] Formal rulemaking always has been the exception, rather than the norm,[27] and it is used infrequently today.

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[21] 5 U.S.C. § 556(d), (e).

[22] 5 U.S.C. § 556 (b).

[23] 5 U.S.C. § 556(d).

[24] 5 U.S.C. § 557(d). This subsection was added by the Government in the Sunshine Act, § 4(a), Pub. L. No. 94-409, 90 Stat. 1241. The amendment was consistent with recommendations of the Temporary Administrative Conference of the United States, 1961-62, Selected Reports of the Administrative Conference of the United States, S. Doc. No. 24, 88th Cong., 1st Sess. 165-205 (1963). For a discussion of "ex parte" or off-the-record contacts in the informal rulemaking context, see Part III, Ch. 6, *infra*.

[25] 5 U.S.C. § 557(c).

[26] For example, 5 U.S.C. § 556(d) provides that in rulemaking "an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form." Also, the separation of functions requirement for adjudication in 5 U.S.C. § 554(d) does not apply to formal rulemaking.

The Supreme Court opened the way for greater use of informal rulemaking in *United States v. Florida East Coast Ry.*,[28] a proceeding to establish future rates. The Court held that section 1(14)(a) of the Interstate Commerce Act did not mandate use of formal rulemaking procedures to establish incentive per diem charges applicable to railroad use of freight cars because that statute only required a decision "after hearing," rather than the precise phrase "on the record after opportunity for an agency hearing" used in section 553(c).[29] There has been much debate on whether the magic words "on the record" must appear in a statute to trigger formal rulemaking.[30] For statutes antedating *Florida East Coast Railway*, they may not, but after that decision one would expect those words to appear in any statute requiring use of formal rulemaking procedure.[31]

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[27] *See* Hamilton, *Procedure for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking*, 60 Calif. L. Rev. 1276, 1278-80 (1972).

[28] 410 U.S. 224 (1973).

[29] 410 U.S. at 241.

[30] *See, e.g.*, Nathanson, *Probing the Mind of the Administrator: Hearing Variations and Standards of Judicial Review Under the Administrative Procedure Act and Other Federal Statutes*, 75 Colum. L. Rev. 721 (1975); K. Davis, Administrative Law of the Seventies 209-240 (1976). *See also* Part III, Ch. 4, *infra*.

[31] For an example of a conscious legislative decision not to include the words "on the record" in a statute, see *Commodity Exchange, Inc. v. CFTC*, 543 F. Supp. 1340, 1345-48 (S.D.N.Y. 1982), *aff'd*, 703 F.2d 682 (2d Cir. 1983). On occasion, the question of whether to provide formal or informal rulemaking will be debated in Congress during the legislative development of a regulatory statute. See discussion in *Industrial Union Dep't v. Hodgson*, 499 F.2d 467, 472-75 (D.C. Cir. 1974).

C. Informal Rulemaking Under Section 553 of the APA

Most agency rulemaking is governed by section 553 of the APA. Unless an exemption is provided, rulemaking under section 553 must comply with the following minimum procedural requirements:

(1) a notice of proposed rulemaking must be published in the Federal Register that includes a statement of the time, place, and nature of the public rulemaking proceedings; a reference to the legal authority under which the rule is proposed; and either the terms or a description of the subjects and issues to be addressed by the proposed rule;[32]

(2) interested persons must be given an opportunity to submit written data, views, or arguments on the proposal, "with or without opportunity for oral presentation;"[33]

(3) a concise general statement of the basis and purpose must accompany the final rule;[34] and

(4) subject to certain exceptions, publication of the final rule must take place "not less than 30 days before its effective date."[35]

Since the opportunity for oral presentation is left to agency discretion (item 2 above), section 553 procedure is accurately referred to as "notice-and-comment" rulemaking. The meaning and operational impact of these procedural requirements will be discussed in detail in later chapters of the guide.[36] The following discussion deals with the numerous exemptions in section 553, under which certain kinds of rules are either totally or partially exempted from its requirements.

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[32] 5 U.S.C. § 553(b). *See* Part III, Ch. 3, *infra.*
[33] 5 U.S.C. § 553(c). *See* Part III, Ch. 4, *infra.*
[34] *Id.* *See* Part III, Ch. 7, *infra.*
[35] 5 U.S.C. § 553(d). *See* Part III, Ch. 7, *infra.*
[36] *See generally* Part III.

D. Rules Exempt From Section 553's Requirements

Two broad categories of rules -- those dealing with military or foreign affairs functions and those relating to agency management or personnel or to public property, loans, grants, benefits, or contracts -- are exempted from all the procedural requirements of section 553.[37] Broad exemptions also exist for other types of rules, such as interpretive rules and procedural rules, and more limited exemptions apply to still other rules, such as rules which relieve restrictions. In carving out these exemptions, the drafters of the APA sought to balance the need for public input with competing societal interests favoring the efficient and expeditious conduct of certain government affairs.[38]

Because these exemptions are exceptions to the APA's general policy of providing an opportunity for public participation in rulemaking, which was designed to foster the fair and informed exercise of agency authority, they have traditionally been "narrowly construed and only reluctantly countenanced."[39]

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[37] 5 U.S.C. § 553(a).

[38] Thus, in *American Hospital Association v. Bowen*, the District of Columbia Circuit stated that the "reading of the § 553 exemptions that seems most consonant with Congress' purposes in adopting the APA is to construe them as an attempt to preserve agency flexibility in dealing with limited situations where substantive rights are not at stake." 834 F.2d 1037, 1045 (D.C. Cir. 1987). *See also Department of Labor v. Kast Metals Corp.*, 744 F.2d 1145, 1153 (5th Cir. 1984) (noting the "tension" between agency efficiency and public input).

[39] *American Fed'n of Gov't Employees, AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981); Bonfield, *Military and Foreign*

The fact that a particular rule is exempted from the public procedures under section 553 does not mean that the exemption is mandatory, nor is it intended to discourage agencies from using public participation procedures. To the contrary, when Congress enacted the APA, it encouraged agencies to use notice and comment in some exempted cases, and many agencies follow notice-and-comment procedure as a matter of course in making certain kinds of exempted rules. Indeed, some agencies have published rules formally waiving section 553 exemptions, and courts have relied on an agency waiver to enforce statutory procedures that otherwise would not apply.[40]

1. Agency Organization, Procedure and Practice

"Rules of agency organization, procedure or practice" are exempted from all of the requirements of section 553.[41] These rules are not, however, exempted from the APA's publication or petition provisions.[42] This exemption has generally covered matters such as agency rules of practice governing the conduct of its proceedings and rules delegating authority or duties within an agency.

Affairs Function Rulemaking Under the APA, 71 Mich. L. Rev. 221, 237 (1972).

[40] *See, e.g., Rodway v. USDA*, 514 F.2d 809 (D.C. Cir. 1975).

[41] 5 U.S.C. § 553(b)(A). The reference to "this subsection" in the clause qualifying the § 553(b) exemptions is misleading because the exemptions also extend to § 553(c)'s comment opportunity. *See* Attorney General's Manual at 30, *reprinted in* ACUS Federal Administrative Procedure Sourcebook.

[42] The drafters of the APA specifically wanted publication of agency rules of practice and procedure so that the public would be aware of them. *See* authorities cited in *Batterton v. Marshall*, 648 F.2d 694, 707 n. 68 (D.C. Cir. 1980). The requirement for publication of procedural rules is at 5 U.S.C. § 552(a)(1), and is discussed *infra*, Part III, Ch. 7.

The exemption has generally been based on the distinction between "procedural" and "substantive" rules -- a slippery distinction that is hard to apply.[43] For a while, the so-called "substantial impact" test had some currency. This test exempted from notice-and-comment requirements agency actions that did not themselves alter the rights or interests of parties, unless the agency action "trenches on substantial private rights and interests."[44] The "substantial impact" test has, however, probably lost much of its impact in the courts of appeals in recent years. Thus, for example, in *American Hospital Association v. Bowen*,[45] the District of Columbia Circuit observed that "[o]ver time our circuit in applying the § 553 exemption for procedural rules has gradually shifted the focus from asking whether a given procedure has a 'substantial impact on parties', . . . to inquiring more broadly whether the agency action also encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior."[46] According to the court, this "gradual move away from looking solely into the substantiality of the impact reflects a candid recognition that even unambiguously procedural measures affect parties to some degree."[47] After analyzing the recent cases on the procedural exemption,[48] the court ruled that HHS's manual governing the procedures for medical peer review inspections in the Medicare program, which was designed to "establish a frequency and focus of PRO [peer review organization] reviews urging its enforcement agents to concentrate their limited resources on particular areas where HHS evidently believes PRO attention will prove most fruitful,"[49] was a procedural rule and therefore not covered by notice-and-comment requirements.[50] In *Southern California Edison Co. v. FERC*,[51] the Ninth Circuit expressly rejected "the notion that procedural rules with a substantial impact are subject to the notice-and-comment requirements," upholding FERC rules pertaining to the procedural aspects of its approval of rates submitted by the Bonneville Power Adminstration.[52]

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[43] *National Motor Freight Traffic Ass'n v. United States*, 268 F. Supp. 90, 96 (D.D.C. 1967), *aff'd*, 393 U.S. 18 (1968) ("[t]he characterizations 'substance' and 'procedural' no more here than elsewhere in the law -- do not guide inexorably to the right result, nor do they really advance the inquiry very far").

[44] *Batterton v. Marshall*, *supra* n. 42, 648 F.2d at 707-08 ("The critical question is whether the agency action jeopardizes the rights and interest of parties.")

[45] *Supra* n. 38.

[46] *Id.*, 834 F.2d at 1047 (citation omitted).

[47] *Id.*

Although the APA provides this exemption for rules of agency procedure or practice, agency rulemakers should consider providing notice and an opportunity for comment where possible if the rules will affect the public. A recent case where a court required notice and comment for administrative rules of practice is *Air Transport Association v. Department of*

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[48] Among others, the court discussed the *Kast Metals* case, discussed *supra* n. 12-17, where the Fifth Circuit held that the Department of Labor's program for selecting employers for workplace safety inspection was a procedural rule, and one which "casts not the stone of substantial impact." 744 F.2d at 1153.

[49] 834 F.2d at 1050.

[50] *Id.* at 1051. The court also ruled that another HHS manual and a program directive containing directions to PROs were likewise procedural. *Id.* at 1051-52.

[51] 770 F.2d 779 (9th Cir. 1985).

[52] *Id.* at 783. *Cf. American Transfer & Storage Co. v. ICC*, 719 F.2d 1283, 1285 (5th Cir. 1983).

Transportation,[53] where the District of Columbia Circuit held that the Federal Aviation Administration's rules of practice for adjudicatory hearings in an administrative civil penalty program were not exempt from notice-and-comment requirements as procedural rules under section 553 (b)(3)(A). The court, emphasizing the "housekeeping nature" of the exemption, stated that the distinction created by the exemption was not between substance and procedure, but between the "rights or interests of regulated parties" and "agencies' internal operations."[54] The court found that the rules "substantially affect . . . defendants' 'right to avail [themselves] of an administrative adjudication,'" and that therefore notice and comment was required.[55] The long-term significance of this case is unclear.[56]

2. *Interpretive Rules and Policy Statements*

"Interpretive rules" and "general statements of policy" are also made exempt from notice-and-comment requirements by section 553(b)(A); moreover, under section 553(d)(2), they can be made effective immediately upon publication in the Federal

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[53] 900 F.2d 369 (D.C. Cir 1990).

[54] *Id.* at 378.

[55] *Id.* The dissent argued that the substance/procedure dichotomy remains meaningful despite its difficulty of application, and citing *American Hospital Association*, that the rules of practice did not "encode a substantive value judgment or put a stamp of approval or disapproval on a given type of behavior"; they in no way affected primary behavior -- in this case safety efforts of airlines.

[56] The District of Columbia Circuit denied a petition for rehearing *en banc* on a 5 to 5 vote, *see* Government's petition for certiorari, filed Oct. 5, 1990, 59 U.S.L.W. 3307 (Oct. 23, 1990)(No. 90-605) at 1. Compare *Southern California Edison Co. v. FERC*, *supra* n. 51 (holding similar rules governing procedural aspects of FERC rate approvals exempt from notice and comment).

Register.[57] They are, however, not exempt from section 553's petition provision or generally, from section 552's publication requirement.[58]

The function of the interpretive rule exemption is "to allow agencies to explain ambiguous terms in legislative enactments without having to undertake cumbersome proceedings."[59] The general policy statement exemption is designed "to allow agencies to announce their 'tentative intentions for the future' . . . without binding themselves."[60] There is general agreement that the public interest is served by prompt dissemination of agency interpretations and policy statements. Moreover, such statements often are indispensible to agency administration, since they guide the staff in its day-to-day tasks and structure the exercise of agency discretion. The exemptions for these agency pronouncements reflect the APA drafters' concern that public participation procedures would delay the issuance of interpretive rules or policy statements and could even discourage agencies from issuing them altogether.[61]

The distinctions between "policy statements" and "interpretive rules," on the one hand, and "substantive" or

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[57] 5 U.S.C. § 553(d)(2). This guide uses the term "interpretive rule" instead of the APA's more cumbersome "interpretative rule".

[58] 5 U.S.C. §§ 553(e). 552(a)(1)(D), (a)(2)(B). It also is noted that Executive Order No. 12,291, § 1(a), defines "regulation" to include agency statements "designed to implement, interpret, or prescribe law or policy or describing the procedure or practice requirements of an agency . . . ."

[59] *American Hospital Ass'n v. Bowen, supra* n. 38, 834 F.2d at 1045.

[60] *Id.* at 1046 (quoting *Pacific Gas & Electric Co. v. FPC*, 506 F.2d 33, 38 (D.C. Cir 1974)).

[61] *See* Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 Mich. L. Rev. 520, 530 (1977).

"legislative" rules[62] requiring notice and comment, on the other, are articulated in the Attorney General's Manual on the APA as follows:

> *Substantive rules* -- rules, other than organization or procedural . . . issued by an agency pursuant to statutory authority and which implement the statute. . . . Such rules have the force and effect of law.
>
> *Interpretative rules* -- rules or statements issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers. [Citations omitted.]
>
> *General statements of policy* -- statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.[63]

The courts' difficulty in applying these distinctions in particular cases shows, however, that the theoretical distinctions between legislative rules, interpretive rules and policy statements tend to break down and become confused in practice. In 1975 the Second Circuit, confronted with a procedural attack on an Immigration and Naturalization Service policy, remarked that the difference between a legislative rule and a general statement of policy is "enshrouded in considerable smog."[64] The metaphor has frequently been referred to by subsequent courts that have been called upon to distinguish between legislative rules and interpretive rules or policy statements.[65]

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[62] The APA distinguishes "substantive rules" from other rules. Today the term "legislative rule" is often used in place of "substantive rule." "Substantive" is generally considered the converse of "procedural," yet interpretive rules and policy statements relate to substance even though they are not "substantive rules" within the meaning of the APA.

[63] Attorney General's Manual at 30 n. 3, *reprinted in* ACUS Federal Administrative Procedure Sourcebook.

[64] *Noel v. Chapman*, 508 F.2d 1023, 1030 (2d Cir. 1975).

Part of the problem is related to the fact that legislative rules, interpretive rules and policy statements all may involve interpretation of a statute. Therefore, sometimes an agency pronouncement can properly be characterized both as an interpretation and a policy statement.[66] Another problem is that sometimes agency actions do not neatly conform to any of these APA categories of pronouncements.[67]

a. "Substantial impact". Dissatisfied with the theoretical distinctions between policy statements, interpretive rules and legislative rules, some courts in the 1970s decided that the determinative factor for deciding if agencies could dispense with notice and comment in announcing policy or interpretations should be whether or not the agency pronouncement had a "substantial impact" on the rights or duties of the public.[68] As in the case of procedural rules, however, the substantial impact test has been abandoned as the sole criterion for deciding whether notice and comment are required for adoption of interpretive rules and policy statements. The District of Columbia Circuit explicitly rejected the substantial impact test as an independent basis for distinguishing interpretive and legislative rules in *Cabais v. Egger.*[69] Citing *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council,*[70] the court stated: "[s]imply because agency action has substantial impact does not mean it is subject to notice and comment if it is otherwise expressly exempt under the APA."[71] A major problem with the substantial impact test, discussed in *Vermont Yankee*[72] and elsewhere[73] is that its imprecise meaning and ad hoc application might cause agencies to routinely provide notice and comment, even where those procedures would serve little purpose.

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[65] *See, e.g., Community Nutrition Institute v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (quoting *Noel* and other sources finding the distinctions to "tenuous", "blurred" and "baffling").

[66] *See, e.g., National Latino Media Coalition v. Federal Communications Commission*, 816 F.2d 785 (D.C. Cir. 1987). An FCC order authorizing use of a tie-breaking lottery where competing applicants for certain licenses were equally qualified was labeled an interpretive rule by the court and described as follows:

> [the FCC statements] merely present an interpretation of the agency's governing statute. They do not bind the Commission ever to conduct a tie-breaker lottery. They do not presently affect the rights and obligations of any license application or of anyone else. They merely serve notice that the Commission believes that it *may*, in some future proceeding, resolve a tie by random selection if one should ever occur.

Id. at 789.

[67] *See, e.g., Community Nutrition Institute v. Young, supra* n. 65 (decision waiving informal "action level" for level of aflatoxin in corn was not an interpretive rule, a policy statement or a "classic legislative rule").

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[68] *See, e.g., Pickus v. U. S. Board of Parole*, 507 F.2d 1107, 1113-14 (D.C. Cir. 1974); *Pharmaceutical Mfrs. Ass'n v. Finch*, 307 F. Supp. 858, 863 (D. Del. 1970).

[69] 690 F.2d 234 (D.C. Cir. 1982). The court stated, however, that the substantial impact test may be one factor used to determine whether an agency action is a policy statement or exempt from notice-and-comment requirements for good cause. *Id.* at 237.

[70] 435 U.S. 519 (1978).

[71] 690 F.2d at 237. *See also Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1016 (9th Cir. 1987); *American Postal Workers Union v. U.S. Postal Service*, 707 F.2d 548, 560 (D.C. Cir. 1983), *cert. denied*, 104 S. Ct. 1594 (1984).

[72] 435 U.S. at 546-47.

[73] Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 Duke L.J. 381, 401.

b. The agency's label. Another issue that has been addressed by courts is whether a reviewing court should, or must, defer to a contemporaneous agency description of its action as an interpretive rule or policy statement. One commentator states that deference to the agency's description of its intention and desired legal effect of its pronouncement "is and should be of central importance in characterizing its product."[74] According to this view, deference to the agency's label promotes certainty and predictability.[75]

However, courts have shown little enthusiasm for this approach. For example, in *Chamber of Commerce v. Occupational Safety and Health Administration*,[76] the District of Columbia Circuit rejected OSHA's characterization of its pronouncement as an interpretive rule, stating:

> Divining agency intent is rarely a simple matter, for bureaucratic boilerplate often obscures the true purpose. The administrative agency's own label is indicative but not dispositive; we do not classify a rule as interpretive just because the agency says it is.[77]

More recently, in *Brock v. Cathedral Bluffs Shale Oil Co.*,[78] the District of Columbia Circuit considered whether a Department of Labor enforcement policy guideline was a policy statement or a legislative rule. The court responded to the

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[74] Asimow, *id.* at 389-90.
[75] *Id.*
[76] 636 F.2d 464 (D.C. Cir. 1980).
[77] *Id.* at 468 (citations omitted).
[78] 796 F.2d 533 (D.C. Cir. 1986).

Secretary of Labor's characterization of its pronouncement as a policy statement by stating that "there is deference and there is deference -- and the degree accorded to the agency on a point such as this is not overwhelming."[79]

A number of reasons have been offered to explain courts' reluctance to defer to an agency's label of its action, including a concern that an agency might label an action an interpretive rule or policy statement to avoid preenforcement judicial review or to circumvent required notice and comment.[80]

c. Policy statements. Making the distinction between policy statements and legislative rules may be somewhat easier than distinguishing interpretive rules from legislative rules. Policy statements are issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power in subsequent adjudications or through rulemaking. Often policy statements are issued to guide agency personnel in administering laws, and sometimes they are addressed to the public.[81]

Perhaps the most concise and clear statement of the attributes of general policy statements is provided in *Pacific*

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[79] *Id.* at 537. *See also Community Nutrition Institute v. Young, supra* n. 65, 818 F.2d at 947 ("courts are to give far greater weight to the language actually used by the agency"); *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc), *cert. denied*, 471 U.S. 1074 (1985) ("the agency's own label, while relevant, is not dispositive").

[80] *See* Asimow, *supra* n. 73, 1985 Duke L. J. at 390.

[81] For a good discussion of the types and uses of policy statements, *see* Asimow, *supra* n. 73, 1985 Duke L.J. at 386-88.

Gas & Electric Co. v. Federal Power Commission,[82] where the court stated that:

> [a] general statement of policy . . . does not establish a "binding norm." It is not finally determinative of the issues or rights to which it is addressed. The agency cannot apply or rely upon a general statement of policy as law because a general statement of policy only announces what the agency seeks to establish as policy.[83]

The District of Columbia Circuit elaborated upon this test in *American Bus Association v. United States*,[84] stating that a policy statement "genuinely leaves the agency and its decisionmakers free to exercise discretion."[85]

The District of Columbia Circuit applied these principles in *Brock v. Cathedral Bluffs Shale Oil Co.*,[86] addressing the question whether certain mine safety enforcement guidelines were "binding norms" to which the Secretary of Labor was required to adhere. In determining that they were policy statements rather than legislative rules, the court focused on the discretion the Secretary retained to apply or not apply the guidelines in particular cases. While stating that the Secretary's characterization of its statement was entitled to some weight, the language used in the statement (*e.g.*, use of words of suggestion, such as "may" rather than inflexible, command words) was far more important.[87] The court concluded that because the guidelines preserved the

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[82] 506 F.2d 33 (D.C. Cir. 1974).
[83] *Id.* at 38 (footnote omitted).
[84] 627 F.2d 525 (D.C. Cir. 1980).
[85] *Id.* at 529.
[86] *Supra* n. 78.
[87] *Id.*, 796 F.2d at 537-38.

Secretary's enforcement discretion, they were therefore not "a binding, substantive regulation."[88]

Similarly, in *Mada-Luna v. Fitzpatrick*,[89] the Ninth Circuit expanded upon the policy statement/legislative rule distinction in finding that INS's operating instructions were exempt from notice-and-comment requirements. The court stated: "To the extent that the directive merely provides *guidance* to agency officials in exercising their discretionary powers while preserving their flexibility and their opportunity to make 'individualized determination[s],' it constitutes a general statement of policy."[90] In contrast, the court said, a rule is legislative to the extent that it "narrowly limits administrative discretion or establishes a '*binding norm*' that 'so fills out the statutory scheme that upon application one need only determine whether a given case is within the rule's criterion.'"[91]

A final example of judicial application of the policy statement/legislative rule distinction is the District of Columbia Circuit's decision in *Community Nutrition Institute v. Young*.[92] *Community Nutrition* involved a challenge to the Food and Drug Administration's (FDA's) decision to allow the marketing of corn containing aflatoxin (a naturally occurring carcinogen) at levels not exceeding 100 parts per billion. The FDA's decision was an exception to a previously-established general "action level" of 20 parts per billion. Both the exception and the general action level were adopted under general statutory authority, without notice and comment, and in lieu of establishing tolerance levels under a specific statute requiring use of an elaborate process resembling formal rulemaking.[93]

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[88] *Id.* at 538.

[89] 813 F.2d 1006 (9th Cir. 1987).

[90] *Id.* at 1013 (emphasis in original).

[91] *Id.* at 1013-14 (emphasis in original).

[92] 818 F.2d 943 (D.C. Cir. 1987).

The Community Nutrition Institute contended in its petition for review that the FDA's action level was a legislative rule and, thus, invalid because FDA failed to follow notice-and-comment procedure in adopting it.[94] FDA, however, argued that action levels "represent nothing more than nonbinding statements of agency enforcement policy."[95] The court concluded that the action level was an invalidly promulgated legislative rule, not a policy statement, because the language used by the FDA "suggests that those levels both have a present effect and are binding,"[96] a conclusion supported by the fact that FDA considered it necessary to publish an exception to the aflatoxin action level and by other agency statements.[97]

d. Interpretive rules. Courts have had much more difficulty distinguishing between interpretive rules and legislative rules. Judge Wald observed in *American Hospital Association v. Bowen*[98] that distinguishing between interpretive and legislative rules is an "extraordinarily case-specific endeavor" and that "analogizing to prior cases is often of limited utility in light of the exceptional degree to which decisions in this doctrinal area turn on their precise facts."[99]

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[93] *See Young v. Community Nutrition Institute*, 476 U.S. 974, 976-77 (1986) (upholding the FDA's decision to proceed by action levels instead of tolerances and discussing the differences between the two procedures).

[94] 818 F.2d at 945.

[95] *Id.* at 945-46.

[96] *Id.* at 947.

[97] *Id.* at 947-48. Judge Starr dissented, arguing that the determinative factor distinguishing legislative rules from policy statements is "whether the pronouncement has the force of law in subsequent proceedings," *id.* at 950; because the FDA disclaimed such effect, he concluded that it could not be a legislative rule, *id.* at 952.

[98] *Supra* n. 38.

In an early case, the District of Columbia Circuit articulated the following test for distinguishing between interpretive and legislative rules:

> Generally speaking, it seems to be established that "regulations," "substantive rules" or "legislative rules" are those which create law, usually implementary to an existing law; whereas interpretative rules are statements as to what the administrative officer thinks the statute or regulation means.[100]

This distinction has come to be referred to as the "legal effect" test: if a rule explaining a statute makes "new law", as opposed to merely interpreting existing law or reminding parties of duties under existing law, then the rule is legislative.[101] Rules have been found to make "new law", and thus to be legislative, where they fill a statutory gap by imposing a standard of conduct, create an exemption from a general standard of conduct, establish a new regulatory structure or otherwise complete an incomplete statutory design.[102]

Agencies need statutorily-delegated authority to adopt legislative rules. This authority may be either specifically delegated[103] or derive from a general grant of rulemaking authority.[104] Legislative rules issued under a statutory delegation and following section 553 procedures are given controlling weight by reviewing courts as long as they are not "arbitrary" or "capricious."[105]

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[99] *Id.*, 834 F.2d at 1045.

[100] *Gibson Wine Co. v. Snyder*, 194 F.2d 329, 331 (D.C. Cir. 1952). This statement recognizes that interpretive rules can interpret previously-adopted agency rules as well as statutes. *See also* Asimow, *supra* n. 61, 75 Mich. L. Rev. at 543.

[101] *See Cabais v. Egger*, 690 F.2d 234, 239 (D.C. Cir. 1982); *Chamber of Commerce v. OSHA*, *supra* n. 76, 636 F.2d at 466-71; *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 877-79 (D.C. Cir. 1979).

[102] *See* Asimow, *supra* n. 73, 1985 Duke L.J. at 394.

Agencies may issue interpretive rules without a delegation of rulemaking authority and without following notice-and-comment procedure. Such interpretive rules do not have the "force of law"; *i.e.*, they are subject to challenge in agency enforcement proceedings and are not entitled to the same degree of judicial deference as legislative rules.[106] It should be noted, however, that some courts have interpreted the Supreme Court's decision in *Chevron U.S.A. v. Natural Resources Defense Council*,[107] to give interpretive rules the same degree of deference accorded legislative rules.[108] This result has been criticized.[109]

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[103] *See, e.g., Batterton v. Francis*, 432 U.S. 416, 425-26 (1977).

[104] *See, e.g., Chrysler Corp. v. Brown*, 441 U.S. 281 (1978); *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672 (D.C. Cir. 1973).

[105] *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984). *See also* Anthony, *Which Agency Interpretations Should Bind Citizens and Courts?*, 7 Yale J. on Reg. 1, 44-46 (1990), *reprinted in* 1989 ACUS Recommendations & Reports 369.

[106] *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944); *National Latino Media Coalition v. FCC*, 816 F.2d 785, 788 (D.C. Cir. 1987). Courts have considered numerous factors in determining how much weight to give to informal interpretations of statutes, including the consistency and duration of the interpretation and the agency's expertise in the matter. *See* Anthony, *supra* n. 105, 7 Yale J. on Reg. at 13-14 nn. 49-52 and accompanying text.

[107] 467 U.S. 837 (1984), discussed Part I(B), *supra*; Part IV, Ch. 2(A)(4), *infra*.

Application of the legal effect test is illustrated by *General Motors Corp. v. Ruckelshaus*[110] in which the District of Columbia Circuit offered "general principles" in defining the difference between "interpretations" and legislative rules.[111] An interpretive rule, the court said, simply states what the agency thinks the statute means and "only 'reminds' affected parties of existing duties" while with a legislative rule, "the agency intends to create new law, rights or duties."[112] Applying these principles, the court found that EPA's rule on the repair of recalled vehicles was interpretive because the agency so regarded it, EPA's "entire justification" for the rule consisted of "reasoned statutory interpretations," and, most importantly, the rule "simply restated" the agency's "consistent practice" in conducting recalls under the statute.[113]

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[108] *See* Anthony, *supra* n. 105, 7 Yale J. on Reg. at 56-57.

[109] *See* Anthony, *id.* at 58 ("an especially odious frustration is visited upon the affected private parties: they are bound by a proposition they had no opportunity to help shape and will have no meaningful opportunity to challenge when it is applied to them"). The Administrative Conference addressed this issue in Recommendation No. 89-5, "Achieving Judicial Acceptance of Agency Statutory Interpretations," 1 C.F.R. § 305.89-5. The Conference recommended that *Chevron* deference only be extended to interpretations of statutes developed through use of procedures such as rulemaking and formal adjudications; other interpretations adopted through less formal formats should be entitled to "such special consideration as their nature and the circumstances of their adoption warrant."

[110] 742 F.2d 1561 (D.C. Cir. 1984) (en banc), *cert. denied*, 471 U.S. 1074 (1985).

[111] *Id.* at 1565.

[112] *Id.* *See also Chamber of Commerce v. OSHA*, *supra* n. 76, 636 F.2d at 469.

[113] 742 F.2d at 1565-66. The principles stated in *General Motors* were followed in *Arrow Air, Inc. v. Dole*, 784 F.2d 1118,

Some recent court decisions have drawn on the "binding norm" language of the District of Columbia's 1974 *Pacific Gas & Electric* decision[114] to distinguish interpretive rules from legislative rules. In so doing, however, these decisions do not clearly distinguish or discuss the various ways agency pronouncements can be binding. First, agency pronouncements may have the intent or effect of binding lower-level agency personnel in implementing laws or regulations. Second, agency pronouncements may have the intent or effect of binding members of the public who are subject to the laws or regulations. Finally, in the case of a validly promulgated legislative rule having the force of law, the agency itself is bound by its terms until it formally amends the rule.

Any form of binding effect will take an agency pronouncement out of the policy statement exemption because policy statements are to have prospective and not immediate effect.[115] However, the analysis is not so simple for interpretive rules. An agency issuing an interpretive rule *(i.e.*, an interpretation which merely reminds parties of existing law or interprets a statute without creating new rights and duties) may well intend that its interpretation bind its own personnel, and it may expect compliance from regulated individuals or entities. Nonetheless, the agency cannot expect the interpretation to be binding in later proceedings; because it does not have the force of law, parties can challenge the interpretation. The agency also is not bound by the

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1122-25 (D.C. Cir. 1986). *See also Jerri's Ceramic Arts v. CPSC*, 874 F.2d 205, 208 (4th Cir. 1989).

[114] *Supra* n. 82.

[115] *See* text at n. 83, *supra*.

interpretation; it can change its interpretation without following notice-and-comment procedures.[116]

A good case illustrating the "fuzziness" of court discussion of the binding norm test as applied to interpretive rules is the District of Columbia Circuit's decision in *State of Alaska v. Department of Transporation*,[117] where the court held that Department of Transportation (DOT) orders exempting certain information from group tour advertisements were invalidly promulgated legislative rules.

The contested DOT orders interpreted regulations that had been properly promulgated in 1984 to implement a statute prohibiting unfair and deceptive advertising by airlines and others. The regulation required tour advertising to include in the advertised price the prices of all parts of the tour package. However, in 1985 DOT issued an "Order Granting Exemption," without notice and comment, which allowed advertisers to exclude from the advertised price a $3 international departure tax that had been enacted by Congress. Then in 1988 DOT issued two more orders exempting various additional surcharges that Congress had enacted in the interim period. Again, these orders were issued without notice and comment.

Twenty-seven states challenged the 1988 orders in court when DOT relied upon them to preempt inconsistent state regulations. The Department's response was that the 1988 orders merely interpreted the 1985 order granting the first exemption from the regulation. The District of Columbia

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[116] *But see Vietnam Veterans v. Secretary of the Navy*, 843 F.2d 528, 536-37 (D.C. Cir. 1988) (discussing whether the maxim requiring agencies to adhere to their own rules extends to interpretive rules or policy statements).

[117] 868 F.2d 441 (D.C. Cir. 1989).

Circuit relied on *Community Nutrition Institute v. Young*[118] (finding an FDA action to be an invalidly promulgated legislative rule and not a policy statement) and reasoned that "while an interpretative rule 'does not impose any rights and obligations' and 'genuinely leaves the agency . . . free to exercise discretion,' a legislative rule is recognizable by virtue of its binding effect."[119] The court, concluded: "[i]n sum, the use of mandatory language cabining DOT's enforcement discretion; DOT's practice of granting "exemptions"; and its decision to publish the 1984 rules in [the Code of Federal Regulations] combine to lead us to the conclusion that the 1988 Orders constitute legislative rules."[120]

Another case applying the "binding norm" test to distinguish interpretive and legislative rules is *Bellarno International v. Food and Drug Administration*.[121] There the district court reviewed a challenge to an FDA "import alert," which the FDA maintained was exempt from notice and comment as an interpretive rule *or* a policy statement.[122] The import alert had the effect of changing the requirements for readmission to the United States of goods originally produced in the United States. The court, also relying on *Community Nutrition Institute* and earlier cases interpreting the policy statement exception, sought to determine whether the FDA import alert was binding on the FDA and the parties. Finding that it was, the court held the action to be invalid for failure to comply with the APA's notice-and-comment requirements.[123]

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[118] *Supra* n. 65.

[119] 868 F.2d at 445.

[120] *Id.* at 447. The court did not mention the legal effect of the DOT's order in an enforcement proceeding. This is noteworthy because Judge Starr, author of the court's opinion, had dissented in *Community Nutrition Institute*, arguing that the "determinative" factor in distinguishing a policy statement from a legislative rule should be whether the pronouncement has the force of law in an enforcement proceeding. *See* n. 97, *supra*.

[121] 678 F. Supp. 410 (E.D. N.Y. 1988).

[122] *Id.* at 412.

These cases suggest that courts often will look at the practical effect of an agency's pronouncement, rather than theoretical distinctions, to decide whether an agency pronouncement is an invalidly promulgated legislative rule or a proper interpretive rule. They may not accept an agency's characterization of its pronouncement or its disclaimer of the "force of law" effect of the pronouncement. If the pronouncement in fact creates new rights or duties and is binding as a practical matter on those affected, then reviewing courts may well require compliance with notice-and-comment procedures.

e. The Administrative Conference's Recommendation. As Judge Wald observed,[124] neither agencies nor affected persons can reliably predict the outcome of a challenge to an agency's use of the APA's exemption for interpretive rules and policy statements. Therefore, agency rulemakers should consider following the Administrative Conference's Recommendation, which urges use of notice-and-comment procedure, where possible, if a rule or statement will have a substantial impact on the public.[125]

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[123] *Id.* at 412-16. Citing *Bellarno* and other cases, the Food and Drug Administration published a proposed rule in July, 1990 to rescind a previously-adopted policy of following notice-and-comment procedure when adopting interpretive rules and policy statements; the FDA stated that "it is not feasible for the agency to follow informal rulemaking procedures for all agency pronouncements that a court might find to be interpretative rules or rules of agency practice and procedure." Department of Health and Human Services, Food and Drug Administration, Proposed Amendment to 21 C.F.R. § 10.40(d), 55 Fed. Reg. 31,080 (1990).

[124] *Supra* nn. 98-99.

The Conference's Recommendation also states that where it is necessary for agencies to make such rules and statements effective immediately, agencies should give the public the opportunity to submit post-promulgation comments.[126] While a post-promulgation comment opportunity is not a *substitute* for pre-promulgation comment where required,[127] it is likely to put the agency in a much better posture on judicial review, especially where it has responded in good faith to post-promulgation comments.[128]

3. *"Good Cause" Exemptions*

Sections 553(b)(B) and 553(d)(3) of the APA authorize agencies to dispense with certain procedures for rules when they find "good cause" to do so. Under section 553(b)(B), the requirements of notice and opportunity for comment do not apply when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Section 553(d)(3) allows an agency, upon finding good cause, to make a rule effective immediately, thereby avoiding the 30-day delayed effective date requirement in section 553.

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[125] Recommendation No. 76-5, "Interpretive Rules of General Applicability and Statements of General Policy," 1 C.F.R. § 305.76-5. Some agencies have followed this advice, *see, e.g.*, EPA, Reporting Requirements for Risk/Benefit Information under Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Final Interpretative Rule and Statement of Policy, 50 Fed. Reg. 38,115, 38,119 (1985) (requesting public comment although rule exempt from public participation requirements of APA as general statement of policy and interpretation of statute).

[126] Recommendation No. 76-5 at ¶2. *See* Asimow, *supra* n. 73, 1985 Duke L.J. at 426 (noting the "modest benefit to the public from a post-adoption comment system would outweigh the modest additional costs that it would impose on agency staffs," and questioning the "much costlier requirement" that would add some form of "substantial impact" test into the APA.)

[127] The general rule that a rule found invalid for failure to provide for notice and comment cannot be saved by providing for comment after promulgation is discussed in *Levesque v. Block*, 723 F.2d 175, 188 (1st Cir. 1988).

[128] *Id. See also* Asimow, *supra* n. 73, 1985 Duke L.J. at 421-24 (discussing the benefits of post-promulgation comments).

These two exceptions give agencies flexibility by allowing them to dispense with procedures in promulgating rules not otherwise exempted, but like other exemptions, they are to be construed narrowly.[129] Moreover, an agency must give supporting reasons for invoking the good cause exemptions.[130] The agency's findings of good cause are judicially reviewable on the same basis as any other findings committed to the agency's judgment.[131] Although the language of the exemption from the delayed effective date requirement is more general than the standard for dispensing with notice and comment, several commentators have concluded that "good cause" under both sections must be predicated on similar findings.[132]

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[129] *See Mobay Chemical Corp. v. Gorsuch*, 682 F.2d 419, 426 (3rd Cir.), *cert. denied*, 459 U.S. 988 (1982); Note, *The "Good Cause" Exceptions: Danger to Notice and Comment Requirements Under the Administrative Procedure Act*, 68 Geo. L.J. 765, 773 (1980).

[130] Senate Comm. on Judiciary, Administrative Procedure Act: Legislative History, S. Doc. 248, 79th Cong., 2d Sess. (hereafter Legislative History of the APA) at 258 (1946). ("The exemption of situations of emergency or necessity is not an 'escape clause' in the sense that any agency has discretion to disregard its terms or the facts. A true and supported or supportable finding of necessity or emergency must be made and published."). 5 U.S.C. § 553(b)(B) requires that the agency "incorporate[] the [good cause] finding and a brief statement of reasons therefor in the rules issued."

[131] *See* Bonfield, *Military and Foreign Affairs Function Rulemaking Under the APA, supra* n. 39, 71 Mich. L. Rev. at 292. Indeed, because public participation has been dispensed with, the courts may scrutinize these rules more carefully than others.

The terms "impracticable," "unnecessary" or "contrary to the public interest" used in section 553(b)(B) indicate the circumstances in which the good cause exceptions may be employed. The APA's legislative history defines the terms this way:

> "Impracticable" means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings. "Unnecessary" means unnecessary so far as the public is concerned, as would be the case if a minor or merely technical amendment in which the public is not particularly interested were involved. "Public interest" supplements the terms "impracticable" or "unnecessary"; it requires that public rulemaking procedures shall not prevent an agency from operating and that, on the other hand, lack of public interest in rulemaking warrants an agency to dispense with public procedure.[133]

Ordinarily, situations potentially covered by the "good cause" exception are those in which advance notice would defeat the agency's regulatory objective; immediate action is necessary to reduce or avoid health hazards or other imminent harm to persons or property; or inaction will lead to serious dislocation in government programs or the marketplace.[134]

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[132] *See* Note, *The "Good Cause" Exceptions*, *supra* n. 129, at 772 n. 61.

[133] Legislative History of the APA, *supra* n. 130, at 200.

[134] *See generally* Jordan, *The Administrative Procedure Act's "Good Cause" Exemption*, 1983 ACUS Recommendations & Reports 49; Jordan, *The Administrative Procedure Act's "Good Cause" Exemption*, 36 Admin. L. Rev. 113 (1984) (based on

Reviewing courts have regularly applied the section 553(b)(B) good cause exemption narrowly to prevent agencies using it as an "escape clause" from notice-and-comment requirements. As the District of Columbia Circuit said in *Action on Smoking and Health v. CAB*,[135] "Bald assertions that the agency does not believe comments would be useful cannot create good cause to forgo notice and comment procedures. . . . To hold otherwise," the court said, "would permit the exceptions to carve the heart out of the statute."[136] The court there held invalid an agency rule issued without notice and an opportunity for comment, where the rule was reissued by the agency to correct a different procedural deficiency in an earlier proceeding in which notice and comment had been provided.[137]

Courts applying the "contrary to the public interest" ground for exemption have often been inclined to err on the side of public safety and health.[138] At the same time, the fact that an action purports to be protective of the public does not necessarily justify not allowing for public participation,

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report to the Administrative Conference). Some enabling statutes contain parallel provisions authorizing agencies to take "emergency" action without affording the normal opportunity for public participation. *See, e.g.*, OSHA Act, 29 U.S.C. § 655(c) (authorizing OSHA to issue a "emergency temporary" occupational safety and health standard where there is a "grave danger" to employees and the standard is "necessary" to protect employees from the "grave danger."

[135] 713 F.2d 795 (D.C. Cir. 1983).

[136] *Id.* at 800 (citations omitted).

[137] The earlier rule was set aside and remanded in *Action on Smoking and Health v. CAB*, 699 F.2d 1209 (D.C. Cir. 1983), on the ground that the agency statement of basis and purpose was insufficent under the APA. *Cf. United Steelworkers v. Pendergrass*, 819 F.2d 1263 (3d Cir. 1987) (holding additional notice and comment unnecessary after court remand on rule).

[138] *See* Jordan, ACUS Report, *supra* n. 134 at 58-59.

particularly where the regulation has wide impact and is controversial. For example, in the famous Baby Doe case,[139] the district court rejected the government's argument that since lives were at stake, "good cause" existed for HHS' issuing its regulation on the treatment of defective newborn infants without notice and comment. The court stated that the argument "could as easily be used to justify immediate implementation of any sort of health or safety regulation no matter how small the risk for the population at large or how long-standing the problem."[140]

In *Asbestos Information Association v. OSHA*,[141] the Fifth Circuit vacated OSHA's asbestos standard issued under a statute authorizing temporary emergency standards where the agency finds that dispensing with notice and comment is "necessary" to protect employees from a "grave danger."[142]

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[139] *American Academy of Pediatrics v. Heckler*, 561 F.Supp. 395 (D.D.C. 1983), *aff'd on other grounds sub nom. Bowen v. American Hospital Ass'n*, 476 U.S. 610, (1986).

[140] 561 F.Supp. at 401. The court emphasized that there was no indication of any "dramatic change in circumstances that would constitute an emergency justifying shunting off public participation in the rulemaking." *Id.* The government's argument that the regulation was "procedural" or "interpretive" was also rejected by the district court, saying that the regulation "was intended . . . to change the course of medical decisionmaking in these cases" and thus was more than a clarification or explanation of an existing rule or statute. *Id.*, quoting *Guardian Federal Savings and Loan v. FSLIC*, 589 F.2d 658, 664 (D.C. Cir. 1978). Apart from its procedural findings, the district court also found the regulation to be invalid as arbitrary and capricious, 561 F. Supp. at 399-400, 403, and expressed concern about the constitutionality of the regulation, *id.* at 402.

[141] 727 F.2d 415 (5th Cir. 1984).

[142] 29 U.S.C. § 655(c). OSHA had issued an earlier asbestos emergency temporary standard in 1972, which was not challenged in court. For a history of OSHA regulation of asbestos to 1983, *see generally* Mintz, OSHA: History, Law and Policy 115-29 (1984).

The court first agreed that an "emergency" standard may lawfully be issued even though new information on grave danger had not come to the attention of the agency.[143] However, the court concluded that the risk assessment analysis used in the rule,[144] while an "extremely useful tool," is "precisely the type of data that may be more uncritically accepted after public scrutiny through notice-and-comment rulemaking, especially when the conclusions it suggests are controversial or subject to different interpretations."[145]

Another "good cause" issue that has arisen with increasing frequency is the extent to which congressionally-imposed deadlines justify an agency's issuance of rules without notice and comment. This issue was addressed in a series of cases challenging EPA's promulgation, without notice and comment, of lists of geographical areas not meeting federal air-quality standards under the Clean Air Act.[146] Courts in five circuits sustained challenges to EPA's action, rejecting its "good cause" argument largely on the ground that EPA could have published the lists as a proposal and obtained public comment with little delay.[147] In these and other similar cases, a factor that often surfaces in the judicial analysis is whether or not the agency made a good faith attempt to comply with the APA's requirements for public participation.

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[143] 727 F.2d at 423. The court of appeals added that the agency must offer some explanation of its timing of the emergency standard, "especially when, as here, for years it has known of the serious risk" and "has possessed, albeit in unrefined form, the substantive data forming the basis" of the standard. *Id. See also American Acad. of Pediatrics, supra* n. 139, 561 F. Supp. at 401.

[144] Risk assesment analysis is a statistical technique utilized by regulatory agencies, among others, for extrapolating risk at high levels of exposure to lower levels. *See generally* Merrill, *Federal Regulation of Cancer-Causing Chemicals*, 1982 ACUS Recommendations & Reports 21, 83-85.

[145] 727 F.2d at 426. The court of appeals also held that the emergency standard was not "necessary" because increased protection of employees could be achieved through more effective enforcement of existing standards. *Id.* at 426-27.

[146] Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685, *codified at* 42 U.S.C. § 7401 *et seq.*

Courts are more inclined to uphold the agency's action if the agency responded to circumstances beyond its control, if the emergency rule is of limited scope or duration, and if the agency initiated prompt follow-up proceedings allowing for public participation.[148] The Fifth Circuit, in *American Transfer & Food Storage v. ICC*,[149] upheld the ICC "good cause" finding that notice and comment was not necessary in issuing rules under the Motor Carrier Act of 1980, saying: "[T]o make the new Act effective and to achieve the goals set by Congress, it was imperative that the Commission, in order to adapt its processes to the new order, adopt almost immediately new rules and procedures with as much notice as was practicable. This it did by issuance of interim rules with invited public input before final regulations were issued."[150] As this case illustrates, however, rules labeled "interim rules" by an agency are final under the APA, and persons "adversely affected or aggrieved" may challenge the rules in court.[151]

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[147] The cases are cited and discussed in Jordan, ACUS Report, *supra* n. 134, at 61-65. *See, e.g., Sharon Steel Corp. v. EPA*, 597 F.2d 377 (3d Cir. 1979). *But see United States Steel Corp. v. EPA*, 605 F.2d 283 (7th Cir. 1979), *cert. denied*, 444 U.S. 1035 (1980) (sustaining good cause finding). *See also* Note: *The "Good Cause" Exceptions: Danger to Notice and Comment Requirements Under the Administrative Procedure Act*, *supra* n. 129.

[148] *See, e.g., Council of the Southern Mountains, Inc. v. Donovan*, 653 F.2d 573 (D.C. Cir. 1981) (upholding Mine Safety and Health Adminstration rule delaying effective date without notice and comment); *Northwest Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309 (8th Cir. 1981) (upholding FAA emergency reduction of comment period and immediate effective date); *National Fed'n of Federal Employees v. Devine*, 671 F.2d 607, 611-12 (D.C. Cir. 1982) (upholding OPM emergency regulations).

[149] 719 F.2d 1283 (5th Cir. 1983).

In a number of decisions, reviewing courts have given greater weight to congressional deadlines in justifying lack of notice and comment when the deadlines implemented budget-cutting measures. In *Philadelphia Citizens in Action v. Schweiker*,[152] the Third Circuit held that HHS had "good cause" for not providing notice and comment in issuing rules to implement changes in the Aid to Families with Dependent Children Program (AFDC).[153] The court relied particularly on the fact that Congress imposed substantially shorter deadlines than those involved in the EPA Clear Air Act cases,[154] and that benefit programs, such as the AFDC program, often are statutorily exempt from notice-and-comment requirements.[155]

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[150] *Id.* at 1294. The Motor Carrier Act became immediately effective and "provided no transition period for developing new procedures to implement the significant legislative changes." *Id.* at 1293. The interim rules were in effect until the final rules were issued.

[151] 5 U.S.C. § 702.

[152] 669 F.2d 877 (3d Cir. 1982).

[153] The changes were mandated by the Omnibus Budget Reconciliation Act (OBRA) of 1981, Pub. L. No. 97-35, 95 Stat. 357.

[154] The OBRA statute was to become effective 49 days after enactment, 669 F.2d at 883, while in the EPA cases, EPA had three years to promulgate the regulations. *Id.* The court of appeals in *Philadelphia Citizens* also noted that EPA would have had sufficient time to allow comment on the unreviewed state-submitted plans under the Clear Air Act, an approach that was not available in the AFDC case. *Id.* at 883-84.

[155] Notice and comment was only required for the regulations involved because HHS in 1971 had waived the exemption in the APA from notice-and-comment requirements for grants and benefits. 669 F.2d at 881. *See also Petry v. Block*, 737 F.2d 1193, 1201 (D.C. Cir. 1984) (involving OBRA of

In many cases, agencies issuing rules without notice and comment following a "good cause" finding have referred to the rules as "interim rules," and then modified the rules, as appropriate, following post-promulgation comment.[156] This practice comports with a Recommendation of the Administrative Conference adopted in 1983.[157] Congress has

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1981); *Sepulveda v. Block*, 782 F.2d 363 (2d Cir. 1986) (involving OBRA of 1982, Pub. L. No. 97-253, 96 Stat. 772).

[156] *See, e.g.*, Department of Transportation, Federal Aviation Administration, "Transportation of Federal Air Marshals," Final Rule with Request for Comments, 50 Fed. Reg. 27,924 (1985). The FAA "emergency rule" required "certificate holders" to carry Federal Air Marshals in designated passenger operations. Because of the "emergency need for the regulations," including hijackings and terrorist attacks on U.S. aviation, the agency found that notice and comment was "impracticable; and contrary to the public interest." However, since under DOT Regulatory Policies and Procedures, 44 Fed. Reg. 11,034 (1979), agencies in the Department "should" provide an opportunity for comment on emergency regulations, the notice invited comment on the "final rule," which was immediately effective, and stated that the comments would be considered and the rule "may be changed in light of the comments received." *Id.* *See also* Department of Agriculture, Animal Plant Health Inspection Service, Imported Fire Ant Regulated Areas, Affirmation of Interim Rule, 50 Fed. Reg. 48,551 (1985). The Department of Labor issued rules implementing the Employee Polygraph Protection Act of 1988, 53 Fed. Reg. 41,494 (1988), making the rule effective on December 27, 1988, the effective date of the Act, but giving an additional two months for comment. *See also* National Oceanic and Atmospheric Administration, Subsistence Taking of North Pacific Fur Seals, Emergency Interim Rule and Request for Comment, 50 Fed. Reg. 27,914 (1985).

[157] Recommendation No. 83-2, "The 'Good Cause' Exemption From APA Rulemaking Requirements," 1 C.F.R. §305.83-2. The Conference recommended that in all cases where an agency is relying on the exemption, it should take the following actions: 1. Frame the rule as "narrowly" as possible to accomplish the regulatory objective; 2. Develop "general criteria" through notice-and-comment rulemaking to be applied in issuing an emergency rule; 3. Promulgate the rule as an "interim" rule to be amended after post-promulgation procedures; 4. In any event, take "appropriate alternative steps" to obtain the views of interested person before adopting the rule.

also expressly authorized this procedure in the context of implementing the 1987 amendments to the Medicare program.[158] Post-promulgation comment will not, however, save a rulemaking where "good cause" did not exist to support exemption from pre-promulgation notice and comment requirements.[159]

A related issue is when an agency may lawfully suspend the effective date of a rule without engaging in notice-and-comment rulemaking. This issue arose after 1981, in connection with the issuance of Executive Order No. 12,291, when some agencies were required to suspend the effective date of a promulgated rule in order to reconsider the costs and benefits under the requirements of the new executive order.[160] Two issues were presented: first, whether suspension was rulemaking under the APA, and, if so, whether "good cause" existed for not providing an opportunity for comment. In *Natural Resources Defense Council v. EPA*,[161] the Third Circuit ruled that EPA's indefinite suspension of rules issued under the Clean Water Act constituted a repeal of the rule.[162] In invalidating the suspension, the court concluded that no justification was shown for eliminating public participation since the agency could have complied with its obligation under both Executive Order No. 12,291 and the APA by providing a brief public comment period.[163] In *Council of the Southern Mountains v. Donovan*,[164] on the other hand, the District of Columbia Circuit upheld a six-month suspension of a mine safety rule where unexpected circumstances made immediate implementation of the rule by the Mine Safety and Health Administration impossible.[165]

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[158] OBRA of 1987, Pub. L. No. 100-203, § 4039(g), *codified at* 42 U.S.C. § 1395hh note.

[159] *But see Levesque v. Block*, 723 F.2d 175, 188 (1st Cir. 1983), suggesting that good faith consideration of post-promulgation comments may support upholding an otherwise invalid rule. *See also* subs. (D)(2)(e), *supra*; Part III, Ch. 4(A), *infra*.

[160] Exec. Order No. 12,291, *reprinted in* 5 U.S.C. § 601 note. Section 7(a) of the order required agencies, with some exceptions, to "suspend or postpone" the effective dates of major rules that were promulgated in final form but had not yet become effective "to the extent necessary to permit reconsideration" under the Order. *See also* Presidential Memorandum Postponing Pending Federal Regulations, Jan. 29, 1981, 1981 Pub. Papers 63.

[161] 683 F.2d 752 (3d Cir. 1982). This and other cases on this issue are discussed in Holmes, *Paradise Postponed: Suspensions of Agency Rules*, 65 N. C. L. Rev. 645 (1987).

As noted above, section 553(b) of the APA provides three separate grounds for the "good cause" finding: "impracticable," "unnecessary," and "contrary to the public interest." The legislative history of the APA defines each of these separately.[166] In practice, agencies often apply the "impracticable" ground together with the "contrary to the public interest" ground, the two being closely related.[167] The "unnecessary" ground for exemption is usually applied to minor technical amendments that involve little exercise of agency discretion.[168] Whatever the agency's basis for the claimed "good cause", however, the agency must articulate its "finding

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[162] The court reasoned that since a rule is defined as an agency statement "of future effect," the effective date is an integral part of the rule and its suspension is a modification of the rule, 683 F.2d at 761-62. The court also relied on the substantial impact of the suspension on the public. *Id.* at 764.

[163] *Id.* at 766.

[164] *Supra* n. 148.

[165] *Id.*, 653 F.2d at 581-82.

[166] *Supra* n. 133.

[167] *See* FAA Notice, *supra* n. 156.

[168] Jordan, ACUS Report, *supra* n. 134, 65-71.

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and a brief statement of reasons therefore in the rules issued."[169]

Some disagreements exist about the appropriate remedy for erroneous use of the good cause exemption from notice and comment. Section 706 of the APA states that "reviewing courts shall . . . hold unlawful and set aside agency action . . . found to be . . . without observance of procedure required by law."[170] Nonetheless, courts sometimes are reluctant to invalidate an otherwise valid rule, especially if it will disrupt on-going programs. Some courts, therefore, have used their equitable powers to fashion relief that balances the need to uphold procedural values with the need for agencies to carry out important programs.[171] Sometimes courts allow the emergency rules to remain in effect pending completion of new proceedings in accordance with the APA.[172] In one case, the court held the agency's rule was valid, but only as an interim measure.[173] On the other hand, courts may well vacate a rule where the "good cause" finding is held to be invalid.[174]

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[169] 5 U.S.C. § 553(b)(B). *See Action on Smoking & Health v. CAB, supra* n. 137, 699 F.2d at 1215-17.

[170] 5 U.S.C § 706(2)(D). This is qualified by a provision that courts may take due account of the rule of prejudicial error. 5 U.S.C. § 706 (last sentence). *See* discussion Part IV, Ch. 2(A)(5).

[171] Jordan, ACUS Report, *supra* n. 134, at 102-03.

[172] *See Western Oil & Gas Ass'n v. EPA*, 633 F.2d 803 (9th Cir. 1980); *United States Steel Corp. v. EPA*, 649 F.2d 572 (8th Cir. 1981).

[173] *American Fed'n of Gov't Employees, AFL-CIO v. Block*, 655 F.2d 1153, 1157 (D.C. Cir. 1981).

[174] *See, e.g., Union of Concerned Scientists v. NRC*, 711 F.2d 370 (D.C. Cir. 1983); *American Iron & Steel Inst. v. EPA*, 568 F.2d 284, 292 (3d Cir. 1977). *Cf. Air Transport Ass'n v. DOT*, 900 F.2d 369 (D.C. Cir. 1990).

Courts have also been unwilling as a general matter to excuse wrongful or erroneous use of the good cause exemption where the agency sought to "cure" the procedural defect by providing an opportunity for public comment after promulgation. Most courts have concluded that post-promulgation comment is not a substitute for comment before rule adoption.[175]

4. Other Exemptions

a. Proprietary matters: public property, loans, grants, and contracts. Section 553(a)(2) of the APA provides an unqualified exclusion from every requirement of section 553 for all rules relating to "public property, loans, grants, benefits and contracts." It should be emphasized, however, that although the scope of these "proprietary" exemptions is quite broad, they apply only where an agency action "clearly and directly" involves one of the exempted matters.[176]

These exemptions, which obviously include many important governmental functions, have been strongly criticized. The Administrative Conference has recommended that the APA be amended to eliminate this exemption and, apart from legislative action, it has urged agencies administering exempt programs to voluntarily use notice-and-comment procedure, without awaiting legislative action.[177] The Recommendation, emphasizing that the rules covered by the exemption "bear heavily upon non-governmental interests,"[178] stated that the exemption was "unwise" and its elimination will "make for fair, informed exercise of rulemaking authority."[179]

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[175] *See, e.g., Natural Resources Defense Council v. EPA*, 683 F. 2d 752, 767-68 (3d Cir. 1982); *Air Transport Association v. DOT, supra* n. 174.

[176] *See* Bonfield, *Public Participation in Federal Rulemaking Relating to Public Property, Loans, Grants, Benefits or Contracts*, 118 U. Pa. L. Rev. 540, 556 (1970).

[177] Recommendation No. 69-8, "Elimination of Certain Exemptions from the APA Rulemaking Requirements," 1 C.F.R. § 305.69-8. Other organizations, such as the Advisory

In 1988, Congress followed the Conference's recommendation when it created the Department of Veterans Affairs (DVA) and required the DVA to use notice-and-comment procedures for virtually all of its regulations.[180] Many departments and agencies with sizeable programs in these areas responded to the Conference's recommendation by issuing rules or policy statements voluntarily waiving or limiting exemptions.[181] The effect of such waivers is to subject the agency to the requirements of section 553 as if it were promulgating non-exempt rules.[182] It should be noted that agencies that waive the exemptions still retain the power to

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Commission on Intergovernmental Relations and the American Bar Association, have also recommended eliminating this exemption.

[178] *Id.* Federal grant, loan, and procurement programs affect the lives of millions of persons and the character of the federal system as a whole. The extent of this impact today is of a far greater magnitude then it was when the APA, with its exemptions, was enacted in 1946.

[179] *Id.*

[180] Pub. L. No. 100-687, 38 U.S.C. § 223.

[181] *See, e.g.*, Department of Transportation Regulatory Policies and Procedures, discussed *supra* n. 156. *See also* Department of Defense, 32 C.F.R. § 296.3 (partial waiver); Housing and Urban Development, 24 C.F.R. § 10.1; Department of Labor, 29 C.F.R. § 2.7 ; HHS, 36 Fed. Reg. 2532 (1971) (policy statement); Department of Agriculture, 36 Fed. Reg. 13,804 (1971) (policy statement); Department of Interior, 36 Fed. Reg. 8,336 (1971) (policy statement); Small Business Administration, 36 Fed. Reg. 16,716 (1971) (policy statement).

[182] Courts have enforced these waivers in numerous instances. *See, e.g., Batterton v. Marshall*, supra n. 42, 648 F. 2d at 700; *Rodway v. USDA*, 514 F.2d 809 (D.C. Cir. 1975). *See also* Yamada, *Rulemaking Requirements Relating to Federal Assistance Programs*, 39 Fed. B.J. 89, 91-93 (1980).

omit notice and comment whenever those procedures are "impracticable, unnecessary, or contrary to the public interest."[183]

Finally, agencies engaged in rulemaking exempted from the APA's procedural requirements by the proprietary exemption may be required by other laws to use some public participation procedures. For example, Executive Order No. 12,291 does not exempt these kinds of rules from its coverage, and it requires covered agencies to make their preliminary and final regulatory analyses available to the public.[184] Also, the Administrator of the Office of Federal Procurement Policy has promulgated regulations providing for notice and the opportunity to comment in rulemaking involving procurement policies.[185]

b. *Agency management and personnel.* Matters "relating to agency management or personnel" are likewise exempted from all requirements of section 553 of the APA.[186] Webster's defines "management" as "the conducting or supervising of something (as a business); esp: the executive function of planning, organizing, coordinating, directing, controlling, and supervising any industrial or business project or activity with responsibility for results."[187] "Personnel" matters generally would include hiring and promotion standards, training, vacation, travel and leave of absence.[188]

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[183] 5 U.S.C. § 553(b)(B). This good cause exemption is applicable to all rules and is discussed *supra*, subs. (D)(3).

The Administrative Conference has recommended that, in order to avoid having to make and publish good cause findings each time it issues a rule, such agencies make a finding to that effect as to an entire subject matter or class of rules and publish it in the Federal Register. Recommendation No. 69-8, *supra* n. 177. The Conference recommended, however, that each finding of this type be no broader than essential and include a statement of underlying reasons.

[184] Exec. Order No. 12,291, §§ 1(a), 3(h).

[185] 41 Fed. Reg. 34,324 (1976) (implementing 41 U.S.C. § 405(d)).

[186] 5 U.S.C. § 553 (a)(2).

This exemption should not be read as intra-agency only. The Attorney General's Manual on the APA construes the exemption to cover many of the management functions now performed by the Office of Management and Budget, as well as interdepartmental committees established by the President for handling internal management problems.[189]

The effect of the personnel exemptions has been reduced somewhat by other statutes, such as the Civil Service Reform Act of 1978, which requires the Office of Personnel Management to follow notice-and-comment procedures in formulating government-wide personnel regulations.[190] Those regulations must be published for comment except where "temporary in nature and . . . necessary to be implemented expeditiously as a result of an emergency."[191]

c. *Military and foreign affairs.* Section 553(a)(1) makes the APA's rulemaking procedures inapplicable "to the extent that there is involved . . . a military or foreign affairs function of the United States." As with proprietary rules, rulemaking involving military or foreign affairs functions is wholly exempted from section 553 requirements.[192]

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[187] Webster's Third New International Dictionary 1433 (1966).

[188] For one of the few cases interpreting the scope of the exemption, see *Stewart v. Smith*, 673 F.2d 485 (D.C. Cir. 1982).

[189] Attorney General's Manual on the APA 18, 27, *reprinted in* ACUS Federal Administrative Procedure Sourcebook.

[190] 5 U.S.C. § 1105.

[191] 5 U.S.C. § 1103(b)(3). *See National Fed'n of Federal Employees v. Devine*, 671 F.2d 607, 610 (D.C. Cir. 1982) (health insurance open season postponement approved). In *Joseph v. U.S. Civil Service Comm'n*, 554 F.2d 1140, 1153, n. 23 (D.C. Cir. 1977), the court of appeals required notice and comment for rules concerning exemptions from the Hatch Act because of their widespread public impact.

The exemptions are not limited to activities of the State and Defense Departments, and, like the proprietary exemptions, they are "not to be loosely interpreted."[193] A report to the Administrative Conference concluded that only rulemaking "directly and intimately" involving these kinds of functions should be exempted.[194]

The Administrative Conference has recommended that Congress replace the categorical exemption for military or foreign affairs functions with a narrower exemption.[195] First, the Conference's Recommendation would make clear that section 553 rulemaking procedures do not apply to matters required by executive order to be kept secret in the interest of national defense or foreign policy.[196] Second, the Conference recommended that repeal of the present exemption "be accompanied by statutory clarification of the agencies' power to prescribe by rule specified categories of rulemaking exempt [by section 553's "good cause" exemption], provided that the appropriate finding and a brief statement of reasons are set forth with respect to each category."[197]

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[192] *See* Bonfield, *Military and Foreign Affairs Function Rulemaking Under the APA*, *supra* n. 39, 71 Mich. L. Rev. at 230-31 (1973). *See also American Ass'n of Exporters & Importers v. U.S.*, 751 F.2d 1239 (Fed. Cir. 1985). The court held that the President may issue regulations to carry out international trade agreements without notice and comment, saying that the purpose of the exemption "was to allow more cautious and sensitive consideration of those matters which 'so affect relations with other Governments that, for example, public rule-making provisions, would provoke definitely undesirable international consequences'." *Id.* at 1249.

[193] Legislative History of the APA, *supra* n. 130, at 9, 257.

[194] Bonfield, *supra* n. 39, 71 Mich. L. Rev. at 236-38, 252-53. Professor Bonfield discusses the scope of the exemptions, including agency views, *id.* at 240-70.

[195] Recommendation No. 73-5, "Elimination of the 'Military or Foreign Affairs Function' Exemption from APA Rulemaking Requirements," 1 C.F.R. § 305.73-5.

[196] *Id.*, ¶ (2)(a). Thus, the exemption would track the language of exemption (b)(1) in the Freedom of Information Act, 5 U.S.C. § 552.

In response to this Recommendation, the Department of Defense issued regulations establishing a general policy favoring notice and comment in the development of regulations having a substantial and direct impact on the public, unless a "significant and legitimate interest" of the Department or the public requires not following that procedure.[198]

d. *Exemptions from delayed effective date requirement.* Section 553(d) states that "[t]he required publication or service of a substantive rule shall be made not less than 30 days before its effective date." There are three exceptions to this requirement, two of which were discussed earlier in connection with section 553 exemptions from notice-and-comment requirements. Interpretive rules and policy statements[199] are not subject to the delayed effective date requirement, nor are rules for which the agency finds and publishes with the rule "good cause" for dispensing with the requirement.[200]

The third exception to the delayed effective date requirement is for "a substantive rule which grants or recognizes an exemption or relieves a restriction."[201] This exemption has no direct counterpart in section 553(b)'s exemptions from notice-and-comment requirements. However, it appears to be merely a more particularized statement of when a requirement is "unnecessary," which is one ground for a "good cause" finding under section 553(b)(B). The primary purpose of the delayed effective date requirement is to give people a reasonable time to prepare to comply with or take other action with respect to the rule.[202]

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[197] *Id.*, ¶2(b).

[198] 32 C.F.R. § 296.3; *see also* 32 C.F.R. § 518.64 for the Department of the Army's regulations defining its procedures relating to public participation in rulemaking.

[199] *See* discussion *supra*, subs. (D)(2).

[200] *See* discussion *supra*, subs. (D)(3). *See U.S. v. Garrilovic*, 551 F.2d 1099 (8th Cir. 1977) (rejecting agency justification for waiver; where consequence of agency rulemaking is to make previously lawful conduct unlawful and to impose criminal sanctions, "heavy burden" placed on agency to establish "public necessity" for waiver.)

The exemptions from the APA's delayed effective date requirement sometimes have been confused with the exemptions from the APA's notice-and-comment requirements.[203] Therefore, we stress that the exemption for rules granting an exemption or relieving a restriction does not apply to section 553's notice-and-comment provisions.[204]

E. Publication Requirements of Section 552 of the APA

While Section 553 of the APA contains most of the procedural requirements imposed on agency rulemaking by the Act, agency rulemakers should not forget that section 552, enacted as part of the Freedom of Information Act, also contains certain requirements applicable to agency rules.[205] Section 552 requires agencies to publish certain items in the Federal Register for the "guidance of the public."[206] The items include "rules of procedure"[207] and "substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency."[208] The section also requires publication of "descriptions of [agency] organization"[209] and "statements of the general course and method by which [the agency's] functions are channeled and determined,"[210] which may be rules as defined in 5 U.S.C. § 551(4). Finally, section 552 specifically directs agencies to publish changes in, or repeals of, their rules and policies.[211]

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[201] 5 U.S.C. § 553(d)(1). *See Independent U.S. Tanker Owners Comm. v. Skinner*, 884 F.2d 587, 591 (D.C. Cir. 1989), *cert. denied*, 110 S. Ct. 1922 (1990) (where rule relieves a restriction, agency need not make an explicit claim in published rule of its right to waive 30-day waiting period.)

[202] *See* Attorney General's Manual on the APA 37, *reprinted in* ACUS Federal Administrative Procedure Sourcebook; Jordan, ACUS Reports, *supra* n. 134, at 78 and n. 199. *See Daniel International Corp. v. OSHRC*, 656 F.2d 925 (4th Cir. 1981) (OSHA's failure to provide full 30-day delayed effective date in 1971 did not invalidate rule as applied to corporation six years later).

[203] Jordan, ACUS Reports, *supra* n. 134, at 77-78.

[204] *Joseph v. Civil Service Comm'n*, *supra* n. 191, 554 F.2d at 1153 n. 23.

While the phraseology of section 552 is different from that used in the section 551 definition of "rule," it appears to encompass almost all of the rules included in section 551, even those exempt from notice-and-comment rulemaking under section 553. The one exception is "rules of particular applicability," which need not be published in the Federal Register.[212] Failure to comply with section 552's publication requirements means that a person may not be required to resort to, or be adversely affected by, a matter "required to be published in the Federal Register and not so published," unless the person has actual and timely notice of the matter.[213]

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[205] 5 U.S.C. § 552.

[206] 5 U.S.C. § 552(a)(1). Much of the language in this section is carried over from Section 3 of the original APA. *See also* Note, *A Model for Determining the Publication Requirements of Section 552(a)(1) of the Administrative Procedure Act*, 13 J. L. Ref. 515 (1980).

[207] 5 U.S.C. § 552 (a)(1)(C).

[208] *Id.*, § D.

[209] *Id.*, § A.

[210] *Id.*, § B.

[211] *Id.*, § E.

[212] Section 552(a)(1)(D) makes the publication requirements applicable to "substantive rules of general applicability" and to

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"statements of general policy or interpretations of general applicability." *See* discussion *infra*, Part III, Ch. 7.

[213] 5 U.S.C. § 552(a)(1). However, despite the straightforward language, some courts have refused to invalidate agency enforcement actions where the agency failed to publish internal guidelines or policies and the challengers could not show they were adversely affected by nonpublication. *See, e.g., Donovan v. Wollaston Alloys, Inc.*, 695 F.2d 1 (1st Cir. 1982); *State of New York v. Lyng*, 829 F.2d 346, 354 (2d Cir. 1987). In *Lyng*, the Second Circuit held that the publication requirement "attaches only to matters which if not published would adversely affect a member of the public." This construction of section 552, the court said, "comports with the stated purpose of providing guidance to the public" and "reconciles the broad language of this provision with the impracticability of publishing all interpretative rulings." *Id.* at 354. *See also Morton v. Ruiz*, 415 U.S. 199, 234-36 (1974) (invalidating an interpretation of the Bureau of Indian Affairs of the Department of the Interior adversely affecting the right of needy Indians to federal financial assistance because it had not been published as required by the Section 552 and the BIA manual of procedures). *See generally* Springer, *Gatekeeping and the* Federal Register*: An Analysis of the Publication Requirement of Section 552(a)(1)(D) of the Administrative Procedure Act*, 41 Admin. L. Rev. 533 (1989).

PART II: THE STATUTORY FRAMEWORK FOR RULEMAKING

CHAPTER 2

RULEMAKING AND ADJUDICATION FOR THE SETTING OF POLICY: A COMPARISON

Enabling statutes typically delegate to administrative agencies the central responsibility for policymaking in the area covered by the statute.[1] It is generally accepted that agencies are free to decide whether to formulate policy through rulemaking or adjudication.[2] This principle follows from the structure of the APA, whose two main procedural sections are entitled "Rule making" and "Adjudications."[3] Apart from rulemaking and adjudication, there are, of course, a variety of informal means by which administrative agencies articulate policy under a statute. Among these are press releases, speeches, statements, letters, advisory opinions, rulings and a host of other types of communications. The extent to which these informal means of articulating policy are binding on the public will vary, but their binding effect usually will be significantly less than that of a "rule" issued after rulemaking, or an "order" after adjudication.[4] As a matter of practice, most significant agency policy decisions result either from rulemaking or adjudication. This chapter discusses the considerations, legal and other, that typically enter into an agency's deliberations in deciding whether to develop policy through rulemaking or adjudication.

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[1] The constitutionality of Congress' delegating to administrative agencies policymaking, *i.e.*, legislative, authority has been frequently questioned. However, not since the 1930s, when the Supreme Court invoked the so-called non-delegation doctrine to strike down portions of the New Deal legislation, *e.g.*, *Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935), has the Court relied on this principle to invalidate a statutory delegation. *See Industrial Union Dep't, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 674-75 (Rehnquist, J., concurring); *American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 543-44 (1981) (Burger C. J. and Rehnquist J., dissenting). *See also Mistretta v. United States*, 488 U.S. 361 (1989) (statute delegating authority to issue sentencing guidelines to U.S. Sentencing Commission does not violate non-delegation doctrine). Among many other articles on the non-delegation doctrine, *see* Schoenbrod, *The Delegation Doctrine: Could The Court Give It Substance?*, 83 Mich. L. Rev. 1223 (1985).

[2] The first major case enunciating this principle was *SEC v. Chenery Corp.*, 332 U.S. 194 (1947), known as *Chenery II*. *See* Weaver, *Chenery II: A Forty-Year Retrospective*, 40 Admin. L. Rev. 161 (1988), and discussion *infra*.

[3] 5 U.S.C. § 553 ("Rule making"), 5 U.S.C. § 554 ("Adjudications").

Some agencies, charged with enforcing regulatory statutes, rely almost exclusively on decisions made in adjudicative proceedings for making policy to be applied in future cases. The National Labor Relations Board (NLRB) has traditionally been considered to be the best example. Over the years, the NLRB was widely criticized by courts and commentators for its failure to use rulemaking.[5] Recently, however, the NLRB too has utilized rulemaking to develop policy on appropriate collective bargaining units for certain facilities in the health care industry.[6]

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[4] *See* ACUS Recommendation No. 89-5, "Achieving Judicial Acceptance of Agency Statutory Interpretations," 1 C.F.R. § 305.89-5. The binding effect of rules is discussed *infra*, subs. (B)(1).

[5] *See, e.g.*, Estreicher, *Policy Oscillation at the Labor Board: A Plea For Rulemaking*, 37 Admin. L. Rev. 163 (1985).

[6] The NLRB issued a final rule concerning collective bargaining units in the health care industry, after two notices

Most other agencies routinely use rulemaking to develop "legislative" policy rules. These rulemaking agencies are typically also charged with bringing enforcement actions against those who violate the statute or the rules issued under their authority. These enforcement proceedings, although adjudicative, frequently also make policy, filling in the interstices of the statute and the agency rules. Thus, most agencies regularly make policy both through rulemaking and adjudication, and are confronted with the problem of choosing the more appropriate route in a particular situation.

A. Legal Constraints on Choosing Rulemaking or Adjudication

1. *Statutory Requirements*

Some agencies have their discretion limited by a statutory mandate requiring them to issue rules on a particular issue. For example, under the Resource Conservation and Recovery Act of 1976 (RCRA),[7] EPA was required to promulgate performance standards for the treatment, storage or disposal of certain hazardous wastes within eighteen months of the statute's enactment, following opportunity for public hearing and consultation with appropriate federal and state agencies.[8] In such situations, the agency must use rulemaking, although the content, timing and procedures used to promulgate the rule

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of proposed rulemaking and three hearings. 54 Fed. Reg. 16,336 (1989).

[7] Pub. L. No. 94-580, 90 Stat. 2796, *amended in* Hazardous and Solid Waste Amendments of 1984, Pub. L. No. 98-616, 98 Stat. 3221, 42 U.S.C. § 6901 *et seq.*

[8] 42 U.S.C. § 6924(a).

may involve significant opportunities for the exercise of agency discretion.[9]

2. *Statutory Authority*

An increasing number of statutes contain explicit authority for the agency to promulgate "legislative" rules. Thus, for example, OSHA is authorized to issue "occupational safety and health standard[s]."[10] The National Highway Traffic Safety Administration is directed to issue motor vehicle safety standards that "shall be practicable, shall meet the need for motor vehicle safety and shall be stated in objective terms."[11] Other statutes, while not explicitly authorizing legislative rules, contain language authorizing agencies to "make such rules and regulations as may be necessary to carry out the provisions" of the act.[12] Such an authorization clearly enables an agency to promulgate procedural, organizational or other "housekeeping" rules,[13] and probably also enables an agency to issue non-binding guidelines or interpretations of its statutory authority. These powers are now quite widely accepted and may even be deemed within an agency's "inherent" authority. Moreover, decisions of the Supreme Court and the District of Columbia Circuit indicate judicial willingness to find legislative rulemaking authority in such language.[14] One of the most significant cases on this issue is *National Petroleum Refiners Association v. FTC*,[15] in which the District of Columbia Circuit construed the Federal Trade Commission's enabling statute, giving the FTC only general "rules and regulations" authority, as authorizing legislative rulemaking by the agency. The court, relying largely on Congress' concern with the "judicial delay, inefficiency and uncertainty" involved in the adjudicatory process, concluded that the "broad undisputed policies" which motivated the framers of the Federal Trade Commission Act of 1914[16] would be furthered by assigning substantive rulemaking authority to the agency.[17]

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[9] The statute limits EPA discretion on the contents of the rules by listing seven types of requirements that must be included in the standards. *Id.* Time limits for completion of agency rulemaking action are common but controversial. The issue is discussed *supra*, Part I (C).

[10] 29 U.S.C. § 655(b).

[11] National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. § 1392.

[12] *See, e.g.*, 29 U.S.C. § 156 (NLRB).

[13] *See* 5 U.S.C. § 301 for specific authority for adoption of "housekeeping" rules.

3. Judicial Constraints

The Supreme Court in *SEC v. Chenery Corporation* (*Chenery II*) first enunciated the general rule that the choice between rulemaking and adjudication is primarily the agency's to make.[18] The case involved the Securities and Exchange Commission's disapproval of a public utility holding company's reorganization on the ground that the reorganization violated standards of fairness derived from the SEC's interpretation of the relevant Act. In effect, the Commission both formulated a rule and applied it in the adjudication before it. The Supreme Court, although observing that "[t]he function of filling in the interstices of the Act should be performed, as much as possible, through the quasi-legislative promulgation of rules to be applied in the future,"[19] ultimately gave the agency the option: "the choice made between proceeding by general rule or by individual, ad hoc litigation," the Court said, "is one that lies primarily in the informed discretion of the administrative agency."[20]

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[14] *See American Paper Institute v. American Electric Power Co.*, 461 U.S. 402, 419 (1983); *E.I. du Pont de Nemours & Co. v. Train*, 430 U.S. 112, 132 (1977); *Mourning v. Family Publications Serv., Inc.*, 411 U.S. 356, 372-73 (1973); *In re Permanent Surface Mining Regulation Litigation*, 653 F.2d 514, 522-24 (D.C. Cir. 1981) (en banc); *Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 873 (D.C. Cir. 1979); *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672 (D.C. Cir 1973), *cert. denied*, 415 U.S. 951 (1974).

[15] *Supra* n. 14.

[16] 15 U.S.C. § 41 *et seq.*

[17] 482 F.2d at 683-87. Two years later, Congress confirmed the FTC's authority to issue legally binding trade regulation rules by enacting the Magnuson-Moss Warranty-Federal Trade Commission Improvement Act. Pub. L. No. 93-637, 88 Stat. 2183, *codified in* 15 U.S.C. § 57a.

[18] *Supra* n. 2.

On the other hand, the Supreme Court encouraged policymaking by rulemaking in *United States v. Storer Broadcasting Co.*[21] In that case, the Federal Communications Commission issued a notice of proposed rulemaking to amend its rules limiting the number of radio and television stations an entity could own or control. After the notice, but before the adoption of the amendment, Storer, which already held the maximum number allowed under the new proposal, applied for an additional station. Storer also participated in the rulemaking proceeding by opposing the proposal, but the Commission adopted the rule and simultaneously dismissed Storer's application for the new station as violative of the new rule. Storer, on judicial review, claimed it was deprived of a "full hearing" which the Commission's rules made a prerequisite to the denial of applications. The Supreme Court upheld the Commission's power to issue such rules and to deny the application without hearing on the basis of the rule. The Court did, however, caution that the rules must be flexible enough to permit applicants to seek amendments or waivers.[22]

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[19] 332 U.S. at 202.
[20] *Id.* at 203.
[21] 351 U.S. 192 (1956).

Storer did not result in any rush by agencies to employ rulemaking, but other agencies and courts did slowly follow its lead. The Federal Power Commission began to use rulemaking to set gas rates, an action previously undertaken through individual trial-type proceedings, and the Supreme Court approved this development in *FPC v. Texaco*[23] and the *Permian Basin Area Rate Cases*.[24] The Civil Aeronautics Board's move toward rulemaking was upheld by the courts despite claims that the rules in effect modified existing certificates without adjudicatory hearings. Especially influential was *American Airlines, Inc. v. CAB*, where Judge Leventhal wrote that "rulemaking is a vital part of the administrative process . . . and . . . is not to be shackled, in the absence of clear and specific congressional requirement, by importation of formalities developed for the adjudicatory process and basically unsuited for policy rulemaking."[25]

As rulemaking became more and more pervasive, the issue no longer was whether rulemaking was a proper mechanism for policymaking. Rather, the arguments focused on whether formulating general policy rules through adjudication constituted a circumvention of the notice-and-comment provisions of section 553 of the APA. This criticism was particularly levelled at the NLRB, whose refusal to employ rulemaking was well-known.

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[22] The Supreme Court relied on *Storer* in *Heckler v. Campbell*, 461 U.S. 458 (1983), upholding HHS's reliance on "medical vocational guidelines" in an adjudicatory proceeding to determine a claimant's right to Social Security benefits. The case is discussed *infra*, subs. (B)(1).

[23] 377 U.S. 33 (1964).

[24] 390 U.S. 747 (1968).

[25] 359 F.2d 624, 629 (D.C. Cir.), *cert. denied*, 385 U.S. 843 (1966).

However, in *NLRB v. Bell Aerospace Co.*,[26] the Supreme Court reaffirmed *Chenery II*'s rule that the choice betwen rulemaking and adjudication is generally the agency's to make. The Supreme Court asserted: "the Board is not precluded from announcing new principles in an adjudicative proceeding . . . the choice between rulemaking and adjudication lies in the first instance within the Board's discretion. Although there may be situations where the Board's reliance on adjudication would amount to an abuse of discretion or violation of the Act, nothing in the present case would justify such a conclusion."[27]

The doctrine that agencies may choose between rulemaking and adjudication has been reaffirmed in a number of recent court decisions.[28] Challenges have, however, continued to come from a variety of directions.

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[26] 416 U.S. 267 (1974).

[27] *Id.* at 294. This case eliminated much of the confusion created by *NRLB v. Wyman-Gordon, Inc.*, 394 U.S. 759 (1969), where the Court, in a badly-split decision, suggested disapproval of the NLRB's practice of promulgating general rules through adjudication, while approving the particular rule at issue.

See also Morton v. Ruiz, 415 U.S. 199 (1974), for a Supreme Court case criticizing agency policymaking in an adjudicatory context as *ad hoc*; this case has not generally been followed. *See* Weaver, *supra* n. 2., 40 Admin. L. Rev. at 186.

[28] *See, e.g.*, *Tearney v. NTSB*, 868 F.2d 1451 (5th Cir. 1989); *Quivira Mining Co. v. NRC*, 866 F.2d 1246, 1261 (10th Cir. 1989).

Some cases, rather than challenging agency policymaking through adjudication, instead sought to force the agency to use adjudicatory procedures to determine the rights of a party. For example, in *Wisconsin Gas Co. v. FERC*,[29] sellers of natural gas challenged certain FERC orders involving the rights of sellers to recover variable costs, on the grounds, among others, that they were based on informal rulemaking. The sellers claimed that since their individual rights were being affected by the orders, they "merited individualized case-by-case adjudication."[30] The District of Columbia Circuit rejected the argument, emphasizing "the breadth and complexity of the Commission's responsibilities" and the "intensely practical difficulties" involved in natural gas regulation.[31] It reaffirmed the principle in *Chenery II* that the choice between proceeding either by general rule or by individual *ad hoc* litigation lies primarily in the "informed discretion of the agency."[32] The court said: "notice and comment rulemaking, particularly appropriate for determination of legislative facts and policy of general, prospective applicability, was a manifestly reasonable method of addressing the systemic problems of the natural gas market."[33]

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[29] 770 F.2d 1144 (D.C. Cir. 1985).

[30] *Id.* at 1165.

[31] The court quoted the Supreme Court decision in the *Permian Basin Area Rate Cases*, 390 U.S. 747 (1968), on this point.

[32] 770 F.2d at 1166, citing 332 U.S. at 202-03.

[33] *Id.* Indeed, in the view of the court of appeals, case-by-case adjudication in these circumstances "may have been entirely inappropriate," since the agency, by applying an adjudicatory order to the individual seller, would be subjecting that seller to unfair competition from other sellers not yet the subject of agency orders. *Id.* at 1166-67 n.36. The court further stated that case-by-case adjudication would open the agency to the objection that it was "unfairly effectuating a

Rulemaking vs. Adjudication

The principle that an agency is free to choose rulemaking or adjudication has also arisen in the context of court suits to compel an agency to institute rulemaking proceedings. In *Arkansas Power & Light Co. v. ICC*,[34] the court, after noting that courts will compel rulemaking only in "extremely rare instances," asserted that an even stronger case for deference to the agency determination exists where the selected alternative to rulemaking is not maintenance of the status quo but "formulation of standards through case-by-case adjudication."[35]

In *Independent U.S. Tanker Owners Comm. v. Lewis*,[36] the court addressed the following issue: "What is the effect of an invalidly promulgated rule upon an adjudicative decision that relies on that rule when the decision, without any rule, would have been within the discretion of the agency?" or, as the court bluntly rephrased the question: "MarAd having botched the rulemaking, the question is whether the subsequent adjudication . . . can still be upheld in its own right."[37] The answer apparently depends on the nature of the rule and its

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general policy change without the necessary industry-wide data and commentary." *Id.* *See also Quivira Mining Co. v. NRC*, *supra* n. 29, 866 F.2d at 1261; *Hercules Inc. v. EPA*, 598 F.2d 91 (D.C. Cir. 1978).

[34] 725 F.2d 716 (D.C. Cir. 1984).

[35] *Id.* at 723. For a case that took a different view, *see Ford Motor Co. v. FTC*, 673 F.2d 1008, *reh. denied id.* at 1010 (9th Cir. 1981), where the Ninth Circuit set aside a FTC cease-and-desist order against a car dealer because the credit practice rule announced there should have been promulgated after rulemaking. This case has been heavily criticized. K. Davis, Administrative Law Treatise §7.25 (Supp. 1982); Berg, *Re-Examining Policy Procedures: The Choice Between Rulemaking and Adjudication*, 38 Admin. L. Rev. 149, 151 n.21 (1986).

[36] 690 F.2d 908 (D.C. Cir. 1982).

[37] *Id.* at 920.

impact on the challenger; in this case, the court refused to invalidate the decision.[38]

B. Practical Considerations in Choosing Rulemaking or Adjudication

Rulemaking and adjudication both can be used to establish standards of conduct for those who are regulated. Both types of decisionmaking can be used to create the necessary predicate for penalizing violators of those standards. They both require the assembly of sufficient factual information to support wise policy judgments. Nevertheless, there are various advantages associated with each procedure.

1. Advantages of Rulemaking

In the last two decades, most commentators have espoused the benefits of rulemaking over adjudication for policymaking. These benefits were recently summarized by one commentator, as follows:[39]

(1) A rule formulated after rulemaking, with its wider notice and broader opportunities for participation, is fairer to the class of persons who would be affected by a new "rule" than a rule announced in an adjudication. Such broader participation also makes rulemaking more efficient as an information-gathering technique for the agency.

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[38] *Id.* at 922.

[39] Berg, *supra* n. 35. *See also* Bonfield, *State Administrative Policy Formulation and the Choice of Lawmaking Methodology*, 42 Admin. L. Rev. 121, 122-36 (1990). *But see* Robinson, *The Making of Administrative Policy: Another Look at Rulemaking and Adjuciation and Administrative Procedure Reform*, 118 U. Pa. L. Rev. 485, 508-13 (1970).

(2) Rulemaking is superior to adjudication as a means of making new law because rulemaking is "normally prospective while adjudication normally involves prescribing consequences for past conduct or present status."[40]

(3) The articulation of a generally applicable rule provides greater clarity to those affected as well as greater uniformity in enforcement.[41]

(4) Rulemaking is more efficient from the agency's point of view because its procedures offer more flexibility, at least when the choice is between the notice-and-comment requirements of section 553 of the APA and the formal adjudicatory procedures of sections 554, 556, and 557. Two of the most significant elements of this flexibility are the agency's broad control over the procedure for the presentation of information and argument and the agency's freedom to resort to its staff expertise without the inhibitions of separation-of-functions requirements.[42]

(5) Since the agency is better able to control the scope and the pace of a rulemaking proceeding, using rulemaking to formulate policy gives the agency better control of its agenda and enables it to define and to focus on the policy issues without the distractions of individual adjudicative issues.

(6) Rulemaking is also more efficient for the agency because it can result in the adoption of a general principle which can thereafter be applied without reexamination, thereby eliminating case-by-case adjudications.[43]

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[40] 38 Admin. L. Rev. at 163.

[41] *Id.*

[42] The separation of functions issue is discussed *infra*, Part III, Ch. 6(E).

[43] Berg, *supra* n. 35, at 163-64.

Another major advantage of policymaking through rules is their broader binding effect. Valid legislative rules are binding and enforceable on the public: that is, they have the force and effect of law.[44] Decisions and orders in an adjudication, on the other hand, are typically binding only on the parties involved, and the rule stated in the proceeding would only have precedential effect in subsequent adjudications. This principle was stated by the District of Columbia Circuit in *National Petroleum Refiners Association v. FTC*,[45] a case upholding the FTC's authority to define violations of the FTC Act through regulations. The court noted that one benefit of rulemaking was that the principal issue in future enforcement cases would simply be whether or not the defendant in fact violated the rule. In that case, the FTC had issued a rule requiring posting of gasoline octane ratings. It therefore would only have to prove whether defendant's gasoline pumps were properly marked with octane ratings. Had no rule requiring postings of octane ratings been promulgated, the FTC would have been obliged to prove that the failure to post was an unfair trade practice, a "laborious process" which might well have to be repeated each time a new enforcement case was brought.[46]

This principle, based on the Supreme Court holding in *Storer Broadcasting* that an agency may rely on a rule promulgated under the informal procedures of the APA to limit the issues to be litigated in a subsequent adjudicative proceeding, was reaffirmed by the Supreme Court in *Heckler v.*

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[44] *Atchison, T. & S.F. Ry. Co. v. Scarlett*, 300 U.S. 171 (1937).
[45] *National Petroleum Refiners Ass'n. v. FTC*, *supra* n. 14.
[46] *Id.*, 482 F.2d at 690-91.

Campbell.[47] In that case, the Secretary of HHS, after notice-and-comment rulemaking, promulgated medical-vocational guidelines to be applied in disability hearings under the Social Security Act to establish the types and numbers of jobs that exist in the national economy. A claimant's qualifications for work were determined on an individual basis, but the guidelines directed the conclusion whether work exists in the national economy that the claimant could perform.[48] The Supreme Court upheld government reliance on the guidelines, saying that although the Social Security Act requires an individualized trial-type determination of the claimant's disability, HHS may resolve a "general factual issue," such as the question of the availability of jobs in the national economy, "as fairly through rulemaking as by introducing the testimony of vocational experts at each disability hearing."[49]

2. *Advantages of Adjudication*

Among the advantages of adjudication and the disadvantages of rulemaking are the following:

(1) Rulemaking's increasing procedural complexity can be avoided. New statutes and executive orders have imposed many new requirements on the rulemaking process. Whatever their benefits in other respects, clearance provisions (OMB review, paperwork reduction provisions), impact statements (regulatory impact analyses, regulatory flexibility analyses),

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[47] 461 U.S. 458 (1983).

[48] *Id.* at 460-62.

[49] *Id.* at 468. *But see Broz v. Heckler*, 711 F.2d 957, 721 F.2d 1297 (11th Cir. 1983) (holding that in disability hearings the effect of claimant's age on his or her ability to work must be determined on a case-by-case basis).

statutes requiring more cumbersome hybrid procedures, and "hard look" judicial review tend to make rulemaking by some agencies a more difficult and protracted venture.[50] If an area is equally susceptible to regulation by adjudication or rulemaking -- where, for example, there are a small number of firms engaged in the regulated activity -- policymaking through adjudication may be seen as more efficient.[51]

(2) Modifications can be made more easily. Specific rules may become obsolete more quickly than more general statutory standards. However, modifications or repeal of rules for policy or technical reasons may be difficult or protracted because a new rulemaking has to be conducted. This may be especially difficult for agencies governed by "hybrid" rulemaking statutes, or for rules defined as "major rules" under Executive Order No. 12,291. Changing policy established by adjudication may, therefore, consume much less time.

(3) Conflict can be minimized. At least one commentator has explained the NLRB's previously steadfast reluctance to abandon the making of policy through adjudication as based on a desire to avoid political conflicts with congressional oversight committees and other overseers.[52] The premise is

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[50] For discussion of these requirements, see Part II, Ch. 3; Part III, Ch. 2; Part IV, Ch. 2, *infra*.

[51] In 1981, Professor (now Justice) Scalia suggested that increased procedural burden on rulemaking might lead agencies to rely more on adjudication for development of policy. Scalia, *Making Law Without Making Rules*, Regulation, July/August 1981, at 25. *See also* J. Mashaw & D. Harfst, The Struggle for Auto Safety (1990) (a detailed account of administration of national highway safety laws, concluding that NHTSA retreated from rulemaking after repeated reversals of rules in court). *Cf.* Berg, *supra* n. 35, at 178 (forseeing no "broad movement away from rulemaking toward adjudication").

[52] Note, *NLRB Rulemaking: Political Reality Versus Procedural Fairness*, 89 Yale L. J. 982 (1980).

that the slow case-by-case accretion of policy is less dramatic or visible, easier to modify, and yet also more impregnable to political attack.[53]

(4) Adjudicatory decisions can be situation-specific, thus potentially avoiding overinclusiveness or underinclusiveness. Rules may unintentionally be overinclusive, reaching unanticipated fact situations, thereby deterring socially desirable behavior or imposing unnecessary costs on society. On the other hand, a rulemaking intended to create a predicate for regulatory sanctions may lead to rules whose terms miss some of the conduct sought to be affected.[54] Subsequent enforcement adjudications may be more easily rebuffed as a result. Related to this problem is one of targeting resources. Enforcement against egregious violators of statutory standards is thought by some to be more cost-effective, less cumbersome, and more politically palatable than attempting to promulgate an industry-wide standard.

The Supreme Court in *NLRB v. Bell Aerospace Co.*[55] focused on a somewhat different reason why some agencies utilize adjudications for certain types of policymaking activity. In concluding that it would have been difficult or impossible for the NLRB to issue a general rule on the determination of managerial status of "buyers" under the National Labor Relations Act for the purpose of determining appropriate units, the Supreme Court said: "There must be tens of thousands of manufacturing, wholesale and retail units which employ buyers, and hundreds and thousands of the latter. Moreover, duties of buyers vary widely depending on the company or industry. It is doubtful whether any generalized standard could be framed which would have more than marginal utility. The Board thus has reasons to proceed with caution, developing its standards in a case-by-case manner with attention to the specific character of the buyers' authority and duty and duties in each company."[56]

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[53] *Id.* The apparent change of the NLRB attitude towards rulemaking is discussed *supra*, text accompanying n. 6.

[54] The over- and under-inclusiveness of rules is discussed in the Administrative Conference's "Statement on Guidelines for Choosing the Appropriate Level of Agency Policy Articulation," 1 C.F.R. § 310.9. *See also* Diver, *The Optimal Precision of Administrative Rules*, 93 Yale L. J. 65 (1983).

[55] *Supra* n. 26.

3. *Summary*

There is thus clearly an interplay between rulemaking and adjudication under the APA. Rules issued after public participation in notice-and-comment proceedings establish general principles that will be binding on the public and applied to individual parties in adjudicatory proceedings. Rulemaking may not ordinarily be used as a substitute for individualized adjudication without implicating due process considerations; however, rules issued after informal proceedings may limit the issues to be adjudicated in subsequent proceedings and reduce the agency burden in establishing statutory violations. Ultimately, however, it is up to the agency to determine which method of policymaking it wishes to use in a particular context.

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[56] 416 U.S. at 294-95 (citation omitted).

PART II: THE STATUTORY FRAMEWORK FOR RULEMAKING

CHAPTER 3

OTHER PROCEDURAL STATUTES AFFECTING RULEMAKING

Previous chapters have described the trend toward imposing procedural requirements on agency rulemaking in addition to those in the APA. In some cases Congress has required a "hybrid" form of rulemaking procedure for particular agencies or agency programs. In other cases, Congress has imposed additional procedural requirements on agencies conducting rulemaking through government-wide statutes. This chapter summarizes these government-wide procedural requirements.[1]

A. The Regulatory Flexibility Act

The Regulatory Flexibility Act[2] directs agencies to consider the potential impact of regulations on small business and other small entities. The Regulatory Flexibility Act mandates consideration of regulatory alternatives, with the anticipated (if unstated) purpose of influencing the substance of the final agency action.

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[1] Additional requirements imposed on a general basis through Presidential executive orders are discussed in Part III, Ch. 2.

[2] 5 U.S.C. §§ 601-12.

Part II: The Statutory Framework

The Regulatory Flexibility Act incorporates the APA's broad definition of "agency,"[3] making it applicable to independent regulatory agencies as well as executive agencies. However, the Act's coverage has important limitations. First, it applies only to rules for which an agency publishes a notice of proposed rulemaking, either pursuant to the APA or some other law, and it does not apply to ratemaking.[4] The Act's flexibility analysis requirements also are limited to rulemaking for which the agency "is *required* by section 553 . . . or any other law, to publish general notice of proposed rulemaking . . . ."[5] Thus, the flexibility analysis requirements do not apply where the agency voluntarily follows notice-and-comment procedure, although they may well be found to apply to rulemaking where the agency has by regulation subjected itself to notice-and-comment procedure.[6]

Through requirements for notice and analysis, the Regulatory Flexibility Act requires agencies to consider the impact of proposed rules on "small entities" -- including "small businesses," "small (not-for-profit) organizations," and "small governmental jurisdictions."[7] The Act does not, however, mandate any particular outcome in rulemaking. It only requires consideration of alternatives that are less burdensome to small entities, and an agency explanation of why alternatives were rejected.[8] Four regulatory alternatives are included in the Act as examples of alternatives to be considered in rulemaking; they are "tiering"; classification and simplification; performance rather than design standards; and exemption.[9]

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[3] *Id.*, § 601(1).

[4] *Id.*, § 601(2) (definition of "rule").

[5] *Id.*, § 603(a) (emphasis added). *See also id.*, at § 604(a).

[6] This interpretation is suggested in Verkuil, *A Critical Guide to the Regulatory Flexibility Act*, 1982 Duke L.J. 213, 240.

[7] The Act contains definitions of these terms, but they are open-ended in the sense that agencies can establish alternative definitions appropriate to their activities. 5 U.S.C. § 601 (3)-(5).

The Act charges the Chief Counsel for Advocacy of the Small Business Administration with overseeing agency compliance with the flexibility analysis requirements. The Office of Advocacy's chief enforcement weapons are publicity, through the requirement of reporting at least annually on agency compliance to the President and Congress,[10] and *amicus* ("friend-of-the-court") appearances in court proceedings involving agency rules.[11]

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[8] 5 U.S.C. § 603(a)(3). The declaration of purpose in the note accompanying 5 U.S.C. § 601 states in part:

> (b) It is the purpose of this Act to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.

It should be pointed out that the agency's explanation, as set forth in any regulatory flexibility analysis, will be part of the "whole record of agency action" if judicial review of a final rule is sought. 5 U.S.C. § 611(b). *See* discussion of judicial review under the Regulatory Flexibility Act, *infra*, Part IV, Ch. 2(A)(5)(b).

[9] 5 U.S.C. § 603(c).

[10] *Id.*, § 612(a). *See, e.g.*, U.S. Small Business Administration, Annual Report of the Chief Counsel for Advocacy on Implementation of the Regulatory Flexibility Act (1983).

[11] 5 U.S.C. § 612(b).

Part II: The Statutory Framework

The Regulatory Flexibility Act operates on the APA rulemaking process in the following fashion:[12] unless the agency head certifies in the Federal Register that the rule will not have a significant economic impact on a substantial number of small entities,[13] an agency must prepare an "initial regulatory flexibility analysis" (IRFA), to be published in the Federal Register along with the proposed rule.[14] The IRFA or the certification must be sent to the Chief Counsel for Advocacy. Where a rule will have a significant economic impact, the agency, in addition to publishing the proposed rule and IRFA in the Federal Register, "shall assure that small entities have been given an opportunity to participate in the rulemaking" through techniques such as advance notice of proposed rulemaking; publication of notice in specialized publications; direct notification of small entities; the holding of public conferences or hearings; or use of simplified or modified procedures that make it easier for small entities to participate.[15] After the comment period on the proposed rule is closed, the agency must prepare a "final regulatory flexibility analysis" (FRFA) which, among other things, responds to issues raised by public comments on the IRFA.[16] The agency is not required to send the FRFA to the Chief Counsel for Advocacy, but it must either publish the FRFA with the final rule or make it available to the public on request.[17]

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[12] For additional discussion of the operation of the Act, see Part III, Ch. 2(C).

[13] 5 U.S.C. § 605(b). *See* Verkuil, *supra* n. 6, at 241, for a discussion of the certification procedure and criteria.

[14] The Act authorizes publication of a summary of the IRFA, 5 U.S.C. § 603(a), an option that should be considered by the agency if the IRFA is lengthy. *See, e.g.*, OSHA's proposed rule on "Air Contaminants", 53 Fed. Reg. 20,960, 21,233, 21,240 (1988).

[15] 5 U.S.C. § 609.

[16] *Id.*, § 604(a).

The Regulatory Flexibility Act also requires agencies to publish and implement a plan for reviewing existing rules on a ten-year cycle.[18] The agency is to review existing rules to minimize "any significant economic impact of the rule on a substantial number of small entities."[19] This review should consider the continued need for the rule; the nature of complaints or comments received concerning the rule; the complexity of the rule; the extent of duplication or conflict with other federal, state, or local regulation, and any relevant economic or technological changes that have occurred since the last review.[20]

Finally, the Regulatory Flexibility Act requires each agency to prepare a regulatory flexibility agenda of rules under development that may have a significant economic impact on a substantial number of small entities.[21] The agenda must be published in the Federal Register semiannually, in October and April, and is to be transmitted to the Office of Advocacy for comment and brought to the attention of small entities or their representatives.[22]

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[17] *Id.*, § 604(b).

[18] 5 U.S.C. § 610(a). The period for review may be extended in one-year increments for up to five additional years. *Id.*

[19] *Id.*, § 610(b). Throughout the Act, the goal of minimizing the impact on small entities is always understood to be considered in the context of achieving objectives of the relevant statute underlying the regulation in question. 5 U.S.C. §§ 603(c), 604(a)(3), 606.

[20] *Id.*, § 610(b).

[21] *Id.*, § 602(a).

[22] 5 U.S.C. § 602(b), (c). Coordination in the implementation of the Regulatory Flexibility Act and Executive Order No. 12,291 is discussed *infra*, Part III, Ch.2(E).

B. The Paperwork Reduction Act

The Paperwork Reduction Act of 1980[23] assigned to the Office of Management and Budget (OMB) the role of coordinating federal information policy. Among the statute's principal purposes are to minimize the federal paperwork burden for individuals, small businesses and state and local governments; to minimize the cost to the federal government of collecting and disseminating information; and to maximize the usefulness to the federal government of the information collected.[24] The Act was amended in 1986 in several important respects, including a change providing that the head of OMB's Office of Information and Regulatory Affairs (OIRA), which was formally established in 1980 by the Act and which has lead responsibility for implementing the Act, be confirmed by the Senate.[25] OMB has issued revised regulations that, among other things, incorporate the statutory modifications.[26]

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[23] 44 U.S.C. §§ 3501-3520, Pub. L. No. 96-511, 94 Stat. 2812 (enacted December 11, 1980), amended by Pub. L. No. 99-500, 100 Stat. 1783-335 and Pub. L. 99-591, 100 Stat. 3341-335. (1986). The 1986 amendments are discussed *infra* n. 25. The Paperwork Reduction Act superceded the Federal Reports Act, Pub. L. No. 77-381 (1942).

[24] 44 U.S.C. § 3501.

[25] 44 U.S.C. § 3503(b), as amended by Pub. L. No. 99-591, 100 Stat. 3341-336. The 1986 amendments also eliminated the confusion that had arisen in connection with the definition of the terms "collection of information" (44 U.S.C. § 3502(4)) and "information collection request" (44 U.S.C. § 3502(11)). By amending the definition in § 3502(11), Congress made it clear that "collection of information requirements" resulting from agency rules are treated in the same manner under the Act as other "collection of information requirements," except as expressly provided under 44 U.S.C. § 3504(b) (clearance procedures, discussed *infra*). *See* OMB, Control of Paperwork Burdens on the Public; Regulatory Changes Reflecting Amendments to the Paperwork Reduction Act, 53 Fed. Reg. 16,618 (1988). Congress in 1986 also added a provision requiring that all communications between the Director of OIRA and agency staff and non-government personnel

The Act's coverage is extremely broad: with a few narrow exceptions, it applies to virtually the entire federal government.[27] The breadth of the Act's coverage also is apparent from the narrowness of the agency functions that are exempted from it. Specific exemptions are provided in section 3518 of Title 44 for (1) federal criminal matters or actions; (2) civil actions and agency litigation or investigation; (3) compulsory process issued in connection with antitrust proceedings; and (4) federal intelligence activities carried out under Presidential executive order.[28] The Act, however, does apply to "general investigations" (other than antitrust investigations) that are "undertaken with reference to a category of individuals or entities such as a class of licensees or an entire industry."[29]

1. The OMB Clearance Requirements

The Paperwork Reduction Act assigns the OMB Director numerous functions, including information collection clearance

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concerning collection of information requests must be made public, with limited exceptions, 44 U.S.C. § 3507(h).

[26] 53 Fed. Reg. 16,618 (1988), *codified at* 5 C.F.R. Part 1320. For further discussion, see Part III, Ch.2.

[27] The Act's definition of "agency" excludes only the General Accounting Office; the Federal Election Commission; the governments of the District of Columbia and the U.S. territories and possessions; and government-owned contractor-operated facilities. 44 U.S.C. § 3502(1).

[28] 44 U.S.C. § 3518(c)(1).

[29] 44 U.S.C. § 3518(c)(2). Through subsequent legislation, Congress has granted exemptions to the Departments of Commerce and Interior under the Marine Mammals Protection Act, and to the Department of Health and Human Services under the Public Health Services Act.

and paperwork control functions.[30] These functions potentially affect agencies engaged in rulemaking.

The Act provides that agencies "shall not conduct or sponsor the collection of information" without first obtaining the approval of the Director of OMB (or his designee.)[31] The Act defines "collection of information" as--

> the obtaining or soliciting of facts or opinions by an agency through the use of written report forms, application forms, schedules, questionnaires, reporting or recordkeeping requirements, or other similar methods calling for either --
>
> (A) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons, other than agencies, instrumentalities, or employees of the United States; or
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> (B) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes.[32]

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[30] The OMB Director's functions are set forth at 44 U.S.C. § 3504(b)-(g).

[31] 44 U.S.C. §§ 3507(a), 3504(h). The Act does not define "sponsor," but OMB has defined the term to apply "if the agency collects the information, causes another agency to collect the information, contracts or enters into a cooperative agreement with a person to collect the information, or requires a person to provide information to another person." 5 C.F.R. § 1320.7(r). This provision also defines the circumstances in which an agency is considered the "sponsor" of a collection of information undertaken by the recipient of a federal grant.

[32] 44 U.S.C. § 3502(4). Inclusion of the word "written" preceding the list of examples of collections of information is misleading. Even under the Federal Reports Act, OMB had authority over use of oral methods to collect information, and that authority continues under the Paperwork Reduction Act. *See* S. Rep. No. 930, 96th Cong., 2d Sess. 39, 54 (1980) (hereinafter cited as "Senate Report").

OMB has interpreted its authority expansively. OMB's regulations define "collection of information" and expand upon the list of methods encompassed by the term.[33] The regulations further state that requirements for disclosure of information to third persons or the public generally "through posting, notification, labeling, or similar disclosure requirements, constitute the 'collection of information' whenever the same requirement . . . would be a 'collection of information' if the information were directly provided to the agency."[34] However, the Supreme Court, in *Dole v. United Steelworkers of America*,[35] held that OMB's authority to approve "collections of information" by federal agencies does not include authority to review agency rules mandating disclosure by regulated entities to third parties.[36]

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[33] "Similar methods," used in the statutory definition, is interpreted by OMB to include--

> contracts, agreements, policy statements, plans, information collection requests, collection of information requirements, rules or regulations, information collection requests or collection of information requirements contained in, derived from, or authorized by such rules or regulations, planning requirements, circulars, directives, instructions, bulletins, requests for proposal or other procurement requirements, interview guides, oral communications, disclosure requirements, labeling requirements, telegraphic or telephonic requests, automated collection techniques, and standard questionnaires used to monitor compliance with agency requirements.

5 C.F.R. § 1320.7(c)(1).

[34] 5 C.F.R. § 1320.7 (c)(2).

[35] 110 S. Ct. 929 (1990).

[36] This case is discussed further *infra*, text accompanying nn. 77-80.

The Act forbids OMB to approve any information collection for a period of more than three years.[37] Failure to obtain OMB approval of a collection of information triggers operation of the Act's public protection provision, which provides that "no person shall be subject to any penalty for failing to maintain or provide information to any agency if the information collection request . . . does not display a current control number assigned by the Director [of OMB], or fails to state that such a request is not subject to [the requirements of the Paperwork Reduction Act]."[38]

2. *Clearance Procedure*

The Paperwork Reduction Act sets out a general set of clearance procedures for approving agency information collections, with more specific clearance procedures prescribed for information collections imposed through notice-and-comment rulemaking.[39]

Section 3504(h) of the Act prescribes the following procedure for clearance of collection of information contained in rules promulgated following notice and comment:

> 1. No later than publication of the notice of proposed rulemaking (NPRM), the agency must submit the rule to OMB, along with any

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[37] 44 U.S.C. § 3507(d).

[38] 44 U.S.C. § 3512. For a discussion of potential pitfalls of this provision of the Act, see Funk, *The Paperwork Reduction Act: Paperwork Reduction Meets Administrative Law*, 24 Harv. J. on Legis. 1 (1987).

[39] While prior OMB regulations, based on the original Act, differentiated between these two kinds of collection of information, the distinctions were eliminated by the 1986 amendments for all purposes except clearance procedures. *See* n. 25, *supra*. See Part III, Ch. 2(B) for additional discussion of information collection requirements in regulations.

background information OMB needs to conduct its review.[40]

2. OMB has 60 days after publication of the NPRM to file comments on the collection of information requirement; if it does not file comments, OMB forfeits its right to disapprove of the requirment.[41]

3. When publishing its final rule, the agency must explain how its rule responds to OMB's comments, or why it rejected the comments.[42]

4. OMB has 60 days from publication of the final rule to disapprove the collection of information provision. Disapproval may be because (a) the agency failed to comply with the submission requirements; (b) the agency substantially modified the collection of information requirement in the final rule without giving OMB 60 days to review the modified requirement; or (c) the agency's response to OMB's comments is found to be "unreasonable."[43]

5. OMB's decision to disapprove the collection of information in the rule, and its reasons for that decision, must be made publicly available.[44]

OMB's regulations implementing the Paperwork Reduction Act have added certain requirements to the clearance procedure for collection of information provisions contained in agency rules. OMB requires, among other things, that:

1. The public always be given a chance to comment on proposed collections of information. In rulemaking, this is accomplished by including in the notice of proposed rulemaking reference to the fact that the rule has been submitted to

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[40] 44 U.S.C. § 3504(h)(1).
[41] *Id.*, § 3504(h)(2), (4).
[42] *Id.*, § 3504(h)(3).
[43] *Id.*, § 3504(h)(5).
[44] *Id.*, § 3504(h)(6).

> OMB for review and that comments may be sent to the OMB desk officer for the agency.[45] The rules also require that the agency include in the preamble to the NPRM a brief statement of the need for the collection of information, a description of the likely respondents, and an estimate of the total annual reporting and recordkeeping burden that will result from each collection of information.[46]
>
> 2. OMB comments on collection of information provisions in rules shall be placed in the agency's rulemaking record.[47]
>
> 3. All collection of information requirements in rules must display an OMB control number; OMB may assign this number when it approves a collection of information provision even if this occurs prior to publication of the final rule.[48]

The Paperwork Reduction Act and OMB's implementing rules establish the following procedure for clearance of information collections not contained in rules issued following notice and comment:

> 1. On or before the day an information collection proposal is submitted to OMB for clearance, the agency must send a notice to the Federal Register, in which the agency advises the public that OMB approval has been requested and that the public may submit comments on the request to the OMB desk officer for the agency. A copy of the notice, and the expected date of its publication in the Federal Register, are to be included in the submission to OMB.[49]
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> 2. Within 60 days after receipt of the agency's submission, OMB will notify the agency of its

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[45] 5 C.F.R. § 1320.13.
[46] *Id.*, § 1320.15(a).
[47] *Id.*, § 1320.13(c).
[48] *Id.*, § 1320.13(f).
[49] 44 U.S.C. § 3507(a)(2); 5 C.F.R. §§ 1320.12(a), 1320.15.

> decision to approve or disapprove, in whole or part, the information collection. OMB may extend the review period for another 30 days.[50]
>
> 3. If OMB does not act within the 60- or 90-day review period, the agency can ask OMB to assign the required control number, and OMB must do so without delay.[51]

OMB has established a separate procedure for clearance of information collections in existing rules.[52] The purpose of these procedures is to prevent OMB's approval for a collection of information to expire before the agency has undertaken the necessary administrative procedure to effect a repeal or amendment of the rule containing the collection requirement.[53] The agency is required to initiate the OMB review process not later then 90 days before the expiration of OMB approval,[54] and if OMB indicates disapproval of the existing requirements the agency is required, consistent with the APA or other applicable requirements, to initiate rulemaking to amend or rescind the collection of information.[55]

The Paperwork Reduction Act contains several variations from the general review procedure for agency information collections. First, the Act establishes a "fast-track" review procedure for emergency situations. Agency heads can request emergency processing under section 3507(g) of the Act, but the tests are stringent.[56] Fast-track review under the statute is likely to be permitted only in situations that would justify use of the "good cause" exemption in section 553 of the APA.[57] OMB has, however, provided by regulation that agencies may request "expedited" processing of collections of information even though the request does not qualify for emergency processing under the statute.[58]

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[50] 44 U.S.C. § 3507(b); 5 C.F.R. § 1320.12(b).
[51] 44 U.S.C. § 3507(b); 5 C.F.R. § 1320.12(c).
[52] This procedure is set forth in 5 C.F.R. § 1320.14.
[53] 5 C.F.R. § 1320.14(a).
[54] *Id.*
[55] 5 C.F.R. § 1320.14(f) and (g). Any amended requirements are also subject to OMB approval. *Id.*

The Act authorizes the OMB Director, following notice and comment, to delegate his approval authority to an agency senior official who "is sufficiently independent of program responsibility to evaluate fairly whether proposed information collection requests should be approved and has sufficient resources to carry out this responsibility effectively."[59] Of course, the agency's senior official must comply with OMB's regulations in reviewing agency information collection requests.[60]

Finally, OMB's general clearance procedure is subject to the Act's provision that independent regulatory agencies may, by majority vote of their members, override an OMB decision disapproving a proposed information collection.[61]

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[56] 44 U.S.C. § 3507(g). This section requires that the collection of information be essential to the mission of the agency, and the agency "cannot reasonably comply" with the normal procedure because (1) public harm will result or (2) an unanticipated event has occurred so that compliance with the usual procedure will nullify the collection of information or cause the agency to miss a statutory deadline.

[57] *See* Part II, Ch. 1(D)(3), *supra*.

[58] 5 C.F.R. § 1320.18(g). If the agency requests expedited review, it is required to publish in the Federal Register notice the time period within which it is requesting OMB to approve or disapprove the collection of information. 5 C.F.R. §§ 1320.15(b)(1), 1320.18(d).

[59] 44 U.S.C. § 3507(e).

[60] *Id.* As of May 10, 1988, OMB had delegated review authority only to the Board of Governors of the Federal Reserve System. 5 C.F.R. § 1320.9(d) and Appendix A to 5 C.F.R. Part 1320.

3. The Standard of Review

The substantive standard governing OMB review of agency information collections is "whether the collection of information by an agency is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility for the agency."[62] OMB's regulations further describe the standard: an agency must show that all reasonable steps have been taken to ensure that the collection of information is the least burdensome necessary, that it is not duplicative of information otherwise accessible to the agency, and that the collection of information has practical utility.[63]

Also pertinent to OMB's authority is section 3518(e), which states:

> Nothing in [the Act] shall be interpreted as increasing or decreasing the authority of the President, the Office of Management and Budget or the Director thereof, under the laws of the United States, with respect to the substantive policies and programs of departments, agencies and offices, including the substantive authority of any Federal agency to enforce the civil rights laws.[64]

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[61] 44 U.S.C. § 3507(c).

[62] 44 U.S.C. §§ 3504(c)(2); 3508. The legislative history does not greatly amplify upon the standard. The Senate committee report states that the "necessity" test includes "whether the collection of information: (1) has practical utility for the agency, (2) is not more than the minimum needed to meet the agency's objective, or (3) is not duplicative of similar information otherwise accessible." Senate Report, *supra* n. 32, at 49.

[63] 5 C.F.R. § 1320.4(b).

[64] 44 U.S.C. § 3518(e).

This provision was added to make clear that, although Congress intended paperwork reduction review to complement substantive review pursuant to existing executive orders, it did not want the Paperwork Reduction Act to be used for general substantive regulatory reform.[65] This was partly out of concern that paperwork and information policy concerns would be subordinated to substantive review.[66]

Through its regulations, OMB has attempted to give content to the broad statutory standard for review of agency paperwork burdens. Any collection of information specifically mandated by statute or court order will be considered "necessary" by OMB,[67] as will any collection of information "specifically required by an agency rule approved or not acted upon by OMB" under the Act.[68] Additionally, OMB has established general guidelines that will be applied unless the agency can demonstrate the need for an exception to them.[69] Among other things, OMB will generally not approve a collection of information that requires reporting more often than quarterly;[70] that requires a response in less than 30 days;[71] that requires respondents to submit more than one original and two copies of a document;[72] that requires persons to retain records (other than health, medical or tax records) for more than three years;[73] that does not attempt to ease the burden for small entities;[74] that requires respondents to submit proprietary, trade secret or other confidential information, unless the agency has instituted permissible procedures to protect the information;[75] or that requires persons to maintain or provide information in a format other than that in which it is customarily maintained.[76]

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[65] *See* Senate Report, *supra* n. 32, at 8-9.

[66] *Id.* at 9.

[67] 5 C.F.R. § 1320.4(c)(1). However, OMB will independently assess any collection of information to the extent that the "agency exercises its discretion in its implementation." *Id.*

[68] 5 C.F.R. § 1320.4(c)(2). OMB will independently assess a collection of information "to the extent that it deviates from the specifications of the rule."

[69] 5 C.F.R. § 1320.6.

[70] *Id.*, § 1320.6(a).

[71] *Id.*, § 1320.6(b).

[72] *Id.*, § 1320.6(c).

In *Dole v. United Steelworkers of America*,[77] the Supreme Court considered OMB's authority to disapprove a requirement contained in OSHA's hazard communication rule,[78] requiring employers on multi-employer worksites to exchange material safety data sheets.[79] The Court concluded that the OSHA requirements were not covered by the Paperwork Reduction Act and that OMB acted beyond its statutory authority in disapproving these requirements. Rejecting OMB's interpretation of the Paperwork Reduction Act, the Court decided that the statutory term "information collection request" encompasses only actions by an agency to acquire information that will be useful to the agency in performing its functions, and does not apply to "disclosure" rules, such as OSHA's requirements for data sheets, which involve transfer of information from employers to third parties. These, the Court held, represent a "substantive regulatory choice" by the agency, designed to protect the public against the dangers of hazardous substances, and not the gathering of information within the meaning of the Paperwork Reduction Act.[80]

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[73] *Id.*, § 1320.6(f).

[74] *Id.*, § 1320.6(h).

[75] *Id.*, § 1320.6(i).

[76] *Id.*, § 1320.4(j).

[77] 110 S. Ct. 929 (1990).

[78] OSHA's hazard communication standard has been the subject of extensive litigation. *See Associated Builders and Contractors, Inc. v. Brock*, 862 F.2d 63 (3d Cir. 1988), and cases cited therein.

[79] These data sheets contain information about hazardous chemicals, including physical and chemical characteristics, the nature of the hazard, exposure limits, and appropriate precautions. 29 C.F.R. § 1910.1200(g).

C. The National Environmental Policy Act

The National Environmental Policy Act (NEPA)[81] is similar to the Regulatory Flexibility Act in that it directs agencies to give special attention to certain values during the decisionmaking process. Under NEPA, the potential impact on the environment of federal agency action, including regulations, must be considered. NEPA directs all agencies of the federal government to include in proposals for "major Federal actions significantly affecting the quality of the human environment" a detailed environmental impact statement (EIS) addressing certain listed subjects and applying substantive criteria set forth in the Act.[82] For proposals where the disposition of available resources is an issue, which would include many rulemakings, a discussion of alternatives is required.[83] This would generally be part of an "environmental assessment," which is used where no EIS is required.[84] The Act requires that rulemaking agencies consult with and get comments from agencies with jurisdiction or expertise on the particular environmental impacts at issue. In addition, the EIS or environmental assessment must be made available for public comment and be made part of the rulemaking record.[85]

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[80] 110 S. Ct. at 933.

[81] 42 U.S.C. §§ 4321-47.

[82] 42 U.S.C. § 4332(C).

[83] 42 U.S.C. § 4332(E).

[84] Where "no significant impact" on the environment would result from the action, neither an EIS nor an environmental assessment may be necessary. *See* 40 C.F.R. §§ 1508.4, 1507.3(b)(2). Some federal agencies have classified rulemakings for NEPA purposes as normally requiring only an environmental assessment. *See* 40 C.F.R. § 1507.3(b); 18

To comply with NEPA, all federal agencies with legislative rulemaking authority should have regulations establishing the procedures for assessing the need for an environmental impact statement and for preparing and obtaining comment on the statement.[86] The Council on Environmental Quality has adopted regulations, binding upon all agencies, that set forth uniform standards for conducting environmental reviews.[87]

C.F.R. § 380.5(b)(12)(Federal Energy Regulatory Comm.); 49 C.F.R. § 1105.6(b)(6)(ICC); 21 C.F.R. § 25.22(a)(6)(FDA). *See Illinois Commerce Comm. v. ICC*, 848 F.2d 1246, 1257 (D.C. Cir. 1988)("it is not at all apparent that a change in procedure alone will not affect the environment -- the new procedure may, for example, lessen the opportunity for environmental groups to influence the agency's final decision. The procedural nature of a regulation does not, therefore, exempt an agency from complying with NEPA and preparing an environmental assessment (EA) or environmental impact statement (EIS) where appropriate").

[85] 42 U.S.C. § 4332(C); 40 C.F.R. § 1505.1.

[86] Illustrative of agency regulations describing procedures for conducting environmental reviews are: Department of Defense, 32 C.F.R. Part 214; Federal Communications Commission, 47 C.F.R. § 1.1301 *et seq.*; Food and Drug Administration, HHS, 21 C.F.R. Part 25.

[87] These regulations were issued pursuant to Exec. Order No. 11,991, 3 C.F.R. 123 (1977 compilation). The Supreme Court has treated these regulations as deserving substantial deference, *Andrus v. Sierra Club*, 442 U.S. 347 (1979). For a discussion of the background and legal effect of CEQ's regulations, *see* Note: *NEPA After Andrus v. Sierra Club: The Doctrine of Substantial Deference to the Regulations of the Council on Environmental Quality*, 66 Va. L. Rev. 843, 849-55 (1980).

The Council's regulations are codified at 40 C.F.R. Parts 1500-1508.[88]

D. The Federal Advisory Committee Act

The Federal Advisory Committee Act[89] regulates the formation and operation of advisory committees by federal agencies. The Administrator of the General Services Administration (GSA) has authority for guiding and coordinating the administration of the Act,[90] and has issued regulations for agencies on management of advisory committee.[91]

The Act defines "advisory committee" to include any committee or similar group (1) established or utilized in the interest of obtaining advice or recommendations for the President or one or more federal agencies and (2) which is not composed wholly of full-time federal officers or employees.[92] Among the Act's requirements, new advisory committees may be established by agencies only after public notice and a determination that the establishment will be in the public interest.[93] Each advisory committee must have a clearly defined purpose, and its membership must be fairly balanced in terms of the points of view represented and the functions to be performed.[94] Meetings of the advisory committees must be open to public observation, subject to the same exceptions as provided in the Government in the Sunshine Act.[95]

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[88] The environmental impact statement requirement has generated a huge volume of caselaw and commentary, the extent of which is suggested by the following law review articles: Leventhal, *Environmental Decisionmaking and the Role of the Courts*, 122 U. Pa. L. Rev. 509 (1974); Rodgers, *A Hard Look at Vermont Yankee: Environmental Law Under Close Scrutiny*, 67 Geo. L.J. 699 (1979); Note: *A New Approach to Review of NEPA Findings of No Significant Impact*, 85 Mich. L. Rev. 191 (1986).

[89] 5 U.S.C. App., Pub. L. No. 92-463, 86 Stat. 770.

[90] Exec. Order No. 12,024, 3 C.F.R. 158 (1977 Compilation).

[91] 41 C.F.R. Subpart 101-6.10

[92] 5 U.S.C. App. § 3.

[93] 5 U.S.C. App. §9(a).

Advisory committees can play an important role in federal agency rulemaking. These committees, normally comprised of experts in the regulatory field involved, representatives of affected interested groups, and federal and state agencies, typically advise agencies on the advisability or content of rulemaking, or on issues while the rulemaking is in progress. Some statutes require the agency to utilize an advisory committee, while others authorize but do not require their use.[96] In some cases, the enabling statute will contain procedural and composition requirements for the advisory committee operating in a particular arena.[97] Many federal agencies have issued their own regulations on advisory committee management and procedures.[98]

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[94] *Id.* at §5. *See Public Citizen v. National Advisory Comm. on Microbiological Criteria for Foods*, 886 F.2d 419 (D.C. Cir. 1989) (dismissal of public interest group challenge under FACA to composition of Department of Agriculture advisory committee affirmed by divided panel).

[95] 5 U.S.C. App. at §10; Government in the Sunshine Act, 5 U.S.C. § 552b.

[96] The OSHA Act, for example, authorizes but does not require the use of advisory committees for the bulk of OSHA occupational safety and health standards, 29 U.S.C. § 656.

[97] *See, e.g.*, 29 U.S.C. § 656. The courts sometimes construe procedural requirements strictly. In one case, the court vacated an OSHA standard regulating a carcinogen because the agency had failed to follow the procedures governing the sequence of advisory committee participation in the rulemaking. *Synthetic Organic Chemical Mfrs. Ass'n v. OSHA*, 506 F.2d 385 (3d Cir. 1974), *cert. denied sub nom. Oil, Chemical & Atomic Workers v. Dunlop*, 423 U.S. 830 (1975).

[98] *See, e.g.*, Department of Education, 34 C.F.R. Part 11; Department of Health and Human Services, 45 C.F.R. Part 11; Consumer Product Safety Commission, 16 C.F.R. Part 1018.

The breadth of the definition of "advisory committee" has provoked uncertainty and some litigation.[99] The Administrative Conference has addressed this question on several occasions, particularly in the context of negotiated rulemaking.[100]

E. The Negotiated Rulemaking Act of 1990

The Negotiated Rulemaking Act of 1990[101] establishes a statutory framework for agency use of negotiated rulemaking to formulate proposed regulations. The Act supplements the rulemaking provisions of the Administrative Procedure Act, clarifying the authority of federal agencies to conduct negotiated rulemaking. It largely codifies the practice of those agencies that had previously used the procedure and incorporates relevant recommendations of the Administrative

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[99] *See Washington Legal Foundation v. Department of Justice*, 691 F. Supp. 483 (D.D.C. 1988), *aff'd sub nom. Public Citizen v. Department of Justice*, 109 S. Ct. 2558 (1989). The case involves the question of the application of the Act to activities of an American Bar Association committee in advising the president concerning nominees for federal judgeships. Another case involving the definition of "advisory committee" is *Natural Resources Defense Council v. Herrington*, 637 F.Supp. 116 (D.D.C. 1986).

[100] *See, e.g.*, Recommendation No. 80-3, "Interpretation and Implementation of the Federal Advisory Committee Act," 1 C.F.R. § 305.80-3; Recommendations No. 82-4 and No. 85-5, "Procedures for Negotiating Proposed Regulations," 1 C.F.R. §§ 305.82-4, 305.85-5. Negotiated rulemaking is discussed more fully *infra*, subs. (E); Part III, Ch. 1(B)(2), and in ACUS, Negotiated Rulemaking Sourcebook (1990).

[101] Pub. L. No. 101-648, 104 Stat. 4969, *codified at* 5 U.S.C. §§ 581-90. See Part III, Ch. 1(B)(2) for a general discussion of the negotiated rulemaking process. At the time this Guide went to press, both the Act and the Alternative Dispute Resolution Act, Pub. L. No. 101-552, 104 Stat. 2736, were due to be codified at 5 U.S.C. §§ 581 *et seq.*

Conference. The Act does not require use of the technique, allowing each agency the discretion whether to employ it.

Negotiated rulemaking emerged in the 1980's as an alternative to traditional procedures for drafting proposed regulations. The essence of the procedure is that in certain situations it is possible to bring together representatives of the agency and the various affected interest groups to negotiate the text of a proposed rule. If they do achieve a consensus, then the resulting rule is likely to be easier to implement and the likelihood of subsequent litigation is diminished. Even in the absence of consensus on a draft rule, the process may be valuable as a means of better informing the regulatory agency of the issues and the concerns of the affected interests.

The Act was intended to clarify agency authority and to encourage agency use of the process. Although the Act sets forth some basic public notice requirements, most of the language is permissive. Congress intended that it not impair any rights otherwise retained by agencies or parties, expressly providing that nothing in the Act "should be construed as an attempt to limit innovation and experimentation with the negotiated rulemaking process or with other innovative rulemaking procedures otherwise authorized by law."[102] Although the Act plainly permits an agency to publish as its own the consensus proposal adopted by the negotiating committee, nothing in the Act *requires* the agency to publish either a proposed or final rule merely because a negotiating committee proposed it.

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[102] 5 U.S.C. § 581.

The Act lists a number of criteria that are to be taken into account when an agency considers whether to use negotiated rulemaking in any particular instance.[103] The required public notice announcing the agency's intent to use the procedure must provide an opportunity, for at least 30 days, for members of the public who believe they are inadequately represented on the negotiating committee to apply for membership or better representation, though the agency retains discretion as to whether to grant such requests.[104] If, after considering the public responses to the published notice of intent to establish a negotiating committee, the agency determines not to do so, then the agency must publish a notice of that fact and the reasons for the decision.[105]

The agency must comply with the Federal Advisory Committee Act in establishing and administering the negotiating committee.[106] To avoid creating new sources of potential litigation, agency procedural actions relating to establishing, assisting, or terminating the committee are not subject to judicial review.[107] However, otherwise available judicial review of a rule resulting from negotiated rulemaking is not affected by the Act, and a reviewing court is not to accord such a rule any greater deference merely because of the procedure followed.[108]

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[103] *Id.* at § 583(a).
[104] *Id.* at § 584.
[105] *Id.* at § 585(a).
[106] *Id.* *See* subs. (D), *supra*.
[107] *Id.* at § 590.
[108] *Id.*

The agency must be represented on the committee, but committee meetings are to be chaired by an impartial "facilitator" or mediator who assists the committee in its deliberations.[109] If the committee reaches consensus on a proposed rule, it transmits to the agency a report containing the proposal.[110] "Consensus" is defined as unanimous concurrence among the interests represented unless the committee agrees on a different definition.[111] If the committee does not reach consensus on a rule, it may transmit to the agency whatever information, recommendations, or other material it considers appropriate.[112] The agency may keep a negotiating committee in existence until promulgation of the final rule, but earlier termination is permitted if the agency or the committee so chooses.[113]

Agencies may contract with private parties or may use government employees to act as facilitators or mediators, or to assist the agency in the "convening" process -- *i.e.*, the initial determination of the feasibility of negotiating a rule and the assembly of an appropriate committee membership.[114] Agencies are authorized to pay expenses of certain committee members in accordance with the Federal Advisory Committee Act, and the Administrative Conference may pay certain expenses at the request of the agency conducting the proceeding.[115]

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[109] *Id.* at §§ 585(b), 586.
[110] *Id.* at § 586(f).
[111] *Id.* at § 582(2).
[112] *Id.* at § 586(f).
[113] *Id.* at § 587.
[114] *Id.* at § 588.

The provisions of the Act terminate after six years,[116] except that they remain in effect for any negotiated rulemaking proceeding pending at that time.[117] Numerous federal agencies conducted negotiated rulemaking proceedings under other authority prior to adoption of the Negotiated Rulemaking Act; thus, termination of this Act clearly does not imply that an agency could no longer undertake a negotiated rulemaking.

During the period of congressional consideration of the Negotiated Rulemaking Act, three other bills were enacted that mandated use of negotiated rulemaking.[118] Each of these laws provided specific and differing procedures for negotiating rules. In the future, the Negotiated Rulemaking Act may serve as a common reference whenever Congress specifically wants an agency to use negotiated rulemaking, replacing this *ad hoc* approach.

F. The Federal Register Act

Recognizing the need for a uniform system for handling the publication of federal regulations, Congress in 1935 passed the

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[115] *Id.* at §§ 588, 589. Funding for this purpose is authorized by section 4 of the Act.

[116] *I.e.*, November 29, 1996.

[117] Section 5 of the Act.

[118] The Carl D. Perkins Vocational and Applied Technology Education Act Amendments (Pub. L. No. 101-392); Hawkins-Stafford Elementary and Secondary School Improvements Amendments (Pub. L. No. 100-297); Price-Anderson Amendments Act of 1988 (Pub. L. No. 100-408).

Federal Register Act.[119] The Act requires the filing of certain documents with the Office of the Federal Register, availability of documents for public inspection, publication of documents in the Federal Register, and permanent codification of rules in the Code of Federal Regulations. Publication of a document in the Federal Register has certain important legal effects; in particular, it provides official notice of the document's existence and contents.[120] The APA gave added importance to the Federal Register by requiring publication in the Register of agency statements of organization, procedural rules, and the public notices mandated for agency rulemaking.[121]

The Office of the Federal Register, together with the Public Printer, is responsible for printing and distributing the Federal Register.[122] Under the Federal Register Act, the Administrative Committee of the Federal Register is required to prescribe, with the approval of the President, regulations for carrying out the Act.[123] These regulations appear in 1 C.F.R. Chapter 1, and deal, among other things, with the format, distribution, and special editions of the Federal Register and the preparation, transmittal and processing of documents.[124] The Office of the Federal Register has prepared a useful guide, *The Federal*

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[119] 44 U.S.C. § 1501 *et seq.* The Act has been amended several times, most recently in 1984, Pub. L. No. 98-497, 98 Stat. 2286.

[120] 44 U.S.C. §§ 1503, 1505, 1507, 1508, 1510.

[121] The APA requirements are discussed throughout the Guide and, in particular, in Part III, Ch. 7.

[122] 44 U.S.C. § 1502.

[123] 44 U.S.C. § 1506.

[124] 1 C.F.R. Parts 1-22. The Administrative Committee of the Federal Register recently modified its regulations to clarify policies and reflect current procedures concerning, for example, reinstatement of expired regulations, and effective dates and time periods. 54 Fed. Reg. 9670 (1989).

Register: What It Is and How To Use It,[125] which describes, with many actual examples, the kinds of documents that appear in the Federal Register and discusses ways to use the Federal Register. A section describing ways to obtain various documents is included. The Office of the Federal Register also publishes a *Document Drafting Handbook*, which explains in some detail how to prepare documents for Federal Register publication.[126]

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[125] Revised, June 1985. The publication is for sale by the Superintendent of Documents, U.S. Government Printing Office.

[126] National Archives of the United States, Office of the Federal Register, Document Drafting Handbook (1986).

FEDERAL AGENCY RULEMAKING

PART III: INFORMAL RULEMAKING IN PRACTICE

As explained in Part Two, informal or "notice-and-comment" rulemaking is the predominant form of federal agency rulemaking. This Part examines in more detail the notice-and-comment requirements of section 553 of the APA. It also discusses the relationship between informal rulemaking procedure and the additional analysis and procedures imposed by presidential executive orders and government-wide procedural statutes.

CHAPTER 1

PRELIMINARY CONSIDERATIONS

Because agencies have increasingly been required by the courts, Congress, and the President to demonstrate the need for, and rationality of, the rules they adopt, the agency process that precedes rulemaking has become significantly more important. This chapter will discuss a number of preliminary considerations that should be taken into account before an agency begins informal rulemaking following the APA procedures.

A. External Considerations

Rulemakings vary significantly in their manner and pace of development, and the events or external interests that "trigger" a rulemaking may be a major factor influencing the way the rulemaking is conducted. Congress, the courts, and the public may be instrumental in causing an agency to undertake a rulemaking.

1. Congressional and Judicial Pressure

Congress operates in several ways to bring about agency rulemaking. Most directly, an agency's enabling statute may require an agency to undertake specific rulemaking actions, frequently within a particular time frame. In some cases, Congress, in the exercise of its oversight function, will hold hearings and issue a Congressional report "recommending" or "urging" agency rulemaking action.[1] There are also frequent informal contacts between agency officials and individual members of Congress or their staff members on specific rulemaking projects.[2] These often result in the agency giving greater or lesser priority to a rulemaking project than it otherwise might have done, or otherwise affect the agency decisionmaking process.

The judiciary too has had an increasing role in triggering rulemaking activity. As discussed elsewhere,[3] there has been an increasing number of cases in which litigants have sought court enforcement of statutory rulemaking deadlines or otherwise challenged agency failure to act. Agencies often must adjust their priorities to comply with court orders issued in such cases. The public response to a court decision ordering agency action, or the court's criticism of the agency in a decision, may bring about a new agency rulemaking action, even where avenues of legal appeal are available to the agency. Indeed, on occasion, the mere filing of a lawsuit may lead to agency action.[4]

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[1] *See* discussion *supra*, Part I(C).

[2] An example of such contacts were discussions between EPA officials and Senator Robert Byrd and his staff regarding EPA's standard under the Clean Air Act for sulfur dioxide. *Sierra Club v. Costle*, 657 F.2d 298, 408-10 (D.C. Cir. 1981), discussed *infra*, Part III, Ch. 6.

[3] *Infra*, Part IV, Ch. 3.

2. *Public Petitions for Rulemaking*

The public too may provide the impetus for rulemaking. Section 553(e) of the APA provides that "[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."[5] This requirement applies "not only to substantive [legislative] rules but also to interpretations and statements of general policy, and to organizational and procedural rules. It applies both to existing rules and to proposed or tentative rules."[6] While the APA itself does not contain any specific procedural requirements respecting agency response to rulemaking petitions, some statutes mandate certain procedures.[7] In addition, the

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[4] For example, OSHA issued an temporary emergency occupational health standard on certain pesticides a month after a public interest group brought an action in a federal district court to compel issuance of the standard even though no court order was issued. *See* Mintz, OSHA: History, Law and Policy 99 & n. 5 (1984).

[5] 5 U.S.C. § 553(e)

[6] Attorney General's Manual on the APA 38 (1947), *reprinted in* ACUS Federal Administrative Procedure Sourcebook.

[7] *E.g.*, Toxic Substance Contol Act, 15 U.S.C. § 2620 (authorizes citizens to petition for rulemaking; EPA must either grant or deny petition within 90 days; if granted, EPA must promptly commence rulemaking; if denied, reasons must be published in the Federal Register; if petition is denied, or no response is made within the specified period, petitioner may seek *de novo* review in a federal district court). *See Environmental Defense Fund v. Thomas*, 657 F. Supp 302 (D.D.C. 1987)

Attorney General's Manual advised that every agency with rulemaking authority should establish and publish procedural rules governing the receipt, consideration and disposition of rulemaking petitions.[8] A number of agencies have issued such rules.[9]

In 1986, the Administrative Conference completed a study of agencies' handling of rulemaking petitions.[10] The Conference's Recommendation based on this report noted that while most agencies have established some procedures governing petitions for rulemaking, "few agencies have established sound practices in dealing with petitions or responded promptly to such petitions."[11] The Conference, therefore, recommended the adoption of basic procedures for the receipt, consideration, and prompt disposition of petitions for rulemaking, including specifications for the address for filing petitions and their contents, maintenance of a public petition file, and provision for prompt notification to petitioners of the disposition, including "a summary explanatory statement."[12] The

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[8] Attorney General's Manual on the APA 38 (1947), *reprinted in* ACUS Federal Adminstrative Procedure Sourcebook.

[9] *See, e.g.*, Nuclear Regulatory Commission, 10 C.F.R. § 2.802-.803; Department of Energy regulations implementing 42 U.S.C. § 6297(b), 10 C.F.R. §§ 430.41-.49; Consumer Product Safety Commission, 16 C.F.R. § 1051.1-.11. *See* Luneburg, *Petitions for Rulemaking, Federal Agency Practice and Recommendations for Improvement*, 1986 ACUS Recommendations & Reports 493 (containing a complete discussion of agency regulations implementing 5 U.S.C. § 553(e)). *See also* Luneburg, *Petitioning Federal Agencies for Rulemaking: An Overview of Administrative and Judicial Practice and Some Recommendations for Improvement*, 1988 Wis. L. Rev. 1 (1988).

[10] Luneburg, *supra* n. 9.

[11] Recommendation No. 86-6, "Petitions for Rulemaking," 1 C.F.R. § 305.86-6, Preamble.

[12] *Id.*, ¶ 1. *See, e.g.*, Department of Interior, Office of Surface Mining Reclamation & Enforcement, Federal

Conference additionally suggested that agencies, among other things, "develop effective methods for providing notice to interested persons that a petition has been filed," and establish "internal management controls to assure the timely processing of petitions," which might include deadlines for completing interim actions and reaching decisions on petitions.[13] Agencies as a matter of practice often invite comment on petitions for rulemaking, either directly,[14] or as a part of a more general notice of proposed rulemaking.[15]

Whether or not an agency has issued regulations on petitions for rulemaking, members of the public would be well-advised to support requests for the initiation of rulemaking with data and legal and policy arguments. These petitions are more likely to result in a favorable response, and court decisions reversing agency refusals to initiate rulemaking have

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Inspection and Enforcement Authority, Notice of Decision on Petition for Rulemaking, 52 Fed. Reg. 21,598-603 (1987) (containing text of agency's letter to petitioner advising that the petition had been granted in part, with an enclosed statement of the reasons for the agency's decision). *See also* Department of Interior regulations, 30 C.F.R. § 700.12.

[13] Recommendation No. 86-6, ¶2.

[14] *See, e.g.*, Federal Aviation Administration (FAA), Regulation of Ultralight Vehicles, Petition for Rulemaking, 50 Fed. Reg. 6312 (1985). The Federal Register notice stated that it was publishing the "substantive parts of the petition for rulemaking," and inviting the public to comment and "assist the FAA in determining the need, if any, for additional rules governing the operation of ultralight vehicles." *Id.*

[15] *E.g.*, Occupational Safety and Health Administration (OSHA), Occupational Exposure to Hepatitis-B Virus and Human Immunodeficiency Virus, Advance Notice of Proposed Rulemaking, 52 Fed. Reg. 45,438 (1987). The notice, referring to two petitions for rulemaking on this subject that had been filed with the agency, concluded that the "appropriate course of action" would be for OSHA to collect further information through the publication of an ANPR. *Id.* at 45,438-39. Advance notices of proposed rulemaking are discussed *infra*, subs. (B)(1).

typically taken place in the context of the agency having denied a petition for rulemaking.[16]

3. Other Influences on an Agency's Decision to Begin Rulemaking

Other entities may also play a role in agency rulemaking activity. Under some regulatory statutes, the agency is required to consult with an advisory committee or panel before initiating its rulemaking proceeding.[17] In other cases, the statute authorizes but does not require the use of an advisory committee in rulemaking.[18]

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[16] *See, e.g., Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983) (ordering OSHA to propose rule regulating ethylene oxide after agency failed to respond promptly to petition for emergency standard); *see also American Horse Protection Ass'n, Inc. v. Lyng*, 812 F.2d 1 (D.C. Cir. 1987); Part IV, Ch. 3, *infra*.

[17] *See, e.g.*, Consumer Product Safety Act, 15 U.S.C. § 2080 (b)(1) (Commission may not issue an advance notice of proposed rulemaking or proposed rule for a consumer product safety rule relating to a risk of cancer or birth defects unless it has received a report from a Chronic Hazard Advisory Panel as to whether the substance contained in the product is a carcinogen, mutagen, or teratogen). *See also* Medical Device Amendments of 1976, 21 U.S.C. §§ 360c(f)(2)(A),(B) (agency must refer petition found not to be deficient to appropriate classification panel under 21 U.S.C. § 360c(b)).

[18] *See, e.g.*, OSH Act, 29 U.S.C. § 656 (authorizing agency to establish standards advisory committee to assist the agency in its standard-setting functions under the Act).

When an advisory committee is established by statute, its composition is typically regulated, *see, e.g.*, 15 U.S.C. § 2077 (composition of CSPC's Chronic Hazard Advisory Panels). Committee action may be subject to time limitations as part of the rulemaking process. *See, e.g.*, OSH Act, 29 U.S.C. § 655(b)(1) (advisory committee must submit recommendation within 90 days, or longer or shorter period as prescribed by OSHA, but in no event longer than 270 days). Advisory committees usually must be chartered under the Federal Advisory Committee Act (FACA), which imposes certain requirements for the functioning of covered advisory committees. 5 U.S.C. App. 2. *See* discussion of FACA, *supra*, Part [illegible], Ch. 3(D).

Preliminary Considerations

Agencies in most cases have insufficient resources to undertake all of the rulemakings that demand attention. As an Administrative Conference report concluded, for example, the Occupational Safety and Health Administration can undertake only a small number of new rulemaking projects a year from among the thousands of hazardous conditions that warrant attention.[19] How the agency chooses the projects to pursue, *i.e.*, its priority system, "is a matter of no small importance to the agency, the regulated industries, and workers [the protected group]."[20]

Since the promulgation of Executive Order No. 12,498, governing the regulatory planning process, the role of the President and OMB in reviewing agency rulemaking priorities has increased markedly.[21] In some cases the enabling statute establishes a priority by mandating agency action within a specific time period. In other cases, the statute only gives the agency general directions in setting priorities.[22] Court orders, individually or taken together, may effectively establish priorities for agency activity by directing action in specific rulemaking proceedings.[23] Indeed, court-directed rulemaking action has been criticized on the ground that the court, arguably without sufficient expertise, sets the agency's rulemaking agenda. Cognizant of this limitation, courts have often accorded agencies considerable deference in their priority setting and resource allocation.[24]

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[19] McGarity & Shapiro, *OSHA Rulemaking Procedures*, 1987 ACUS Recommendations & Reports 79, 83.

[20] *Id.* at 124.

[21] Exec. Order No. 12,498 is discussed *supra*, Part I(D).

[22] *See, e.g.*, 29 U.S.C. § 655(g) (OSH Act) (stating that agency should give "due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments.")

[23] Court orders requiring agency rulemaking actions are discussed *infra*, Part IV, Ch. 3.

Priority setting thus falls largely on the agency itself; this is not, however, an easy task. The Administrative Conference addressed the issue of setting priorities in the context of carcinogen regulation in Recommendation 82-5, "Federal Regulation of Cancer Causing Chemicals." Recognizing that estimates of the number of carcinogens describe a universe "larger than government agencies can evaluate or regulate," the Conference concluded that a "prioritization system" is necessary to ensure that the chemicals posing the greatest risk and the ones that can be controlled the most economically get the most attention.[25]

B. Procedural Decisions

Once the agency has determined that it will undertake a rulemaking, there are some preliminary procedures it can use that may simplify the process in the long run. One is to seek preliminary views from the public on issues before it formulates a definite agency approach, by use of an advance notice of proposed rulemaking. Another is to consider the use of negotiated rulemaking to develop a proposed rule.

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[24] *See, e.g., National Congress of Hispanic Americans v. Marshall*, 626 F.2d 882, 889 (D.C. Cir. 1979) ("With its broader perspective, and access to a broad range of undertaking . . . the agency has a better capacity than the court to make the comparative judgments involved in determining priorities [in rulemaking] and allocating resources.").

[25] 1 C.F.R. § 305.82-5, Preamble to § 1. It suggested that the priority setting procedure should permit interested members of the public to submit their views and information.

Preliminary Considerations

1. *Advance Notice of Proposed Rulemaking*

The APA does not provide for the publication by an agency of an advance notice of proposed rulemaking (ANPR).[26] However, some regulatory statutes, such as the Federal Trade Commission Improvements Act[27] and the Energy Policy and Conservation Act,[28] require that rulemaking begin with an ANPR.[29] An ANPR notifies the public that an agency is considering an area for rulemaking and usually requests written comments on the appropriate scope of the rulemaking or on specific topics.

An ANPR may be useful to the agency in a variety of circumstances. For example, an agency may seek public comment on what its regulatory response should be to a petition for rulemaking or other "triggering" events. In such circumstances, the Federal Register notice is often entitled "Request for Comment on Petition for Rulemaking" or "Receipt of Petition" or a similar title.[30] In other circumstances, the agency has decided (or been required) to undertake rulemaking but seeks information from the public to assist it in framing the notice of proposed rulemaking.[31] This latter type of advance notice of proposed rulemaking can be extremely helpful in narrowing the issues during the public comment period on the proposed rule, with obvious advantages both to the public and the agency.[32]

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[26] In 1976, the Administrative Conference recommended that agencies consider, in appropriate circumstances, voluntarily publishing an ANPR in order to "solicit comments and suggestions with respect to the contents" of the forthcoming notice of proposed rulemaking. Recommendation No. 76-3, "Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking," 1 C.F.R. § 305.76-3, ¶ 1(a).

[27] 15 U.S.C. § 57a(b)(2)(A). Under this provision, the advance notice must contain a brief description of the "area of inquiry under consideration," the "objectives" FTC seeks to achieve, and possible regulatory alternatives. The notice must also invite a response from interested parties, including suggestions or alternative methods to achieve the regulatory alternatives. The FTC must submit the advance notice to the appropriate Senate and House committees. *Id.*, § 57a(b)(2)(B).

[28] 42 U.S.C. § 6295 (i).

[29] *See also* Medicare and Medicaid Patient and Program Protection Act, Pub. L. 100-93; 101 Stat. 680 §14 (1987) (requiring an advance notice of proposed rulemaking for Medicare anti-kickback regulations).

While the value of the ANPR as a preliminary step in rulemaking is suggested by its frequent use by some agencies, it is also potentially subject to overuse, or even abuse. In several cases, OSHA's resort to an ANPR in a particular situation was viewed by the court as evidence of agency procrastination in the face of its obligation to proceed quickly with important rulemaking activity.[33] A report to the Administrative Conference on OSHA rulemaking noted that there was "a general feeling among agency staff and outside petitioners that [the ANPR] rarely results in the production of useful information for OSHA. Outside parties are simply unwilling to scour their files for information at this [pre-notice of proposed rulemaking] stage," and if the information is available, the parties are unwilling to make it public and "incur the risk of revealing or foreclosing later strategies."[34]

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[30] *See, e.g.*, FAA notice, *supra* n. 14.

[31] *See, e.g.*, OSHA notice, discussed *supra* n. 15; 52 Fed. Reg. 38,794 (1987) (preliminary notice for Medicare anti-kickback regulations).

[32] Thus, the OSHA notice referred to *supra*, n. 15, requested comments on fourteen specific issues.

[33] *United Steelworkers of America v. Pendergrass*, 819 F.2d 1263, 1268 (3rd Cir. 1987) (challenge to OSHA's failure to promptly issue a revised rule on hazard communication in response to court's remand; court was extremely critical of OSHA's having published an ANPR to supplement the original record: "Some of the questions [in the ANPR] could hardly have been posed with the serious intention of obtaining meaningful information since the answers are self-evident." OSHA was directed to act on remand within a 60-day period.) Neither the OSHA statute, 29 U.S.C. § 655(b), nor OSHA's regulations on rulemaking procedures, 29 C.F.R. § 1911.10-.19, requires advance notices of proposed rulemaking.

2. *Negotiated Rulemaking*

In 1990, Congress endorsed the use by agencies of an alternative procedure known as "negotiated rulemaking".[35] This procedure, sometimes called "regulatory negotiation" or "reg-neg", has been used by several agencies to bring interested parties into the rule drafting process at an early stage, under circumstances that foster cooperative efforts to achieve solutions to regulatory problems. Where successful, negotiated rulemaking can lead to better, more acceptable rules, based on a clearer understanding of the concerns of all affected interests. Negotiated rules may be easier to enforce and less likely to be challenged in litigatation.

Absent special circumstances, the Administrative Procedure Act requires an agency planning to adopt a rule on a particular subject to publish a proposed rule in the Federal Register and to offer the public an opportunity to comment.[36] However, the APA does not specify who is to draft the proposed rule nor any particular procedure to govern the drafting process. Ordinarily, agency staff performs this function, with full discretion to determine how much opportunity for public input to allow. Any agency contacts with regulated parties or the general public while the agency is considering or drafting a proposed rule are usually informal and unstructured. Typically, there is no opportunity for interchange of views among potentially affected parties, even where an agency chooses to conduct a hearing.

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[34] McGarity & Shapiro, *OSHA Regulation: Regulatory Alternatives and Legislative Reform*, 1987 ACUS Reports & Recommendations 999, 1046. The Administrative Conference recommended that the agency not routinely use ANPRs as an information-gathering technique, and that they be used only when information not otherwise available "is likely to be forthcoming" in response to the ANPR. Recommendation No. 87-10, "Regulation by the Occupational Safety and Health Administration," 1 C.F.R. § 305.87-10, ¶ 3(e).

[35] Negotiated Rulemaking Act of 1990, Pub. L. No. 101-648, 104 Stat. 4969, *to be codified at* 5 U.S.C. §§ 581-90. See Part II, Ch. 3(E) for a discussion of the Act.

The dynamics of the rulemaking process tend to encourage interested parties to take extreme positions in their written and oral statements -- in pre-proposal contacts as well as in comments on any published proposed rule. They may choose to withhold information that they view as damaging. A party may appear to put equal weight on every argument, giving the agency little clue as to the relative importance it places on the various issues. There is usually little willingness to recognize the legitimate viewpoints of others. The adversarial atmosphere often contributes to the expense and delay associated with regulatory proceedings as parties try to position themselves for the expected litigation. What is lacking is an opportunity for the parties to exchange views and to focus on finding constructive, creative solutions to problems.[37]

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[36] *See* Part III, Chs. 3, 4, *infra*.

[37] For a good discussion of the dynamics of "traditional" notice-and-comment rulemaking, *see generally* Harter, *Negotiating Regulations: A Cure For Malaise*, 71 Geo. L. J. 1 (1982).

Preliminary Considerations

In negotiated rulemaking, the agency, with the assistance of one or more neutral advisers known as "convenors," assembles a committee of representatives of all affected interests to negotiate a proposed rule. The goal of the process is to reach consensus on a text that all parties can accept. The agency is represented at the table by an official who is sufficiently senior to be able to speak authoritatively on behalf of the agency. Negotiating sessions, however, are led not by the agency representative, but by a neutral mediator or facilitator skilled in assisting in the resolution of multi-party disputes.

Negotiated rulemaking is clearly not suitable for all agency rulemaking. The Negotiated Rulemaking Act sets forth several criteria to be considered when an agency determines whether to use reg-neg.[38] These include (1) whether there are a limited number of indentifiable interests -- usually not more than 25, including any relevant government agencies -- that will be significantly affected by the rule; (2) whether a balanced committee can be convened that can adequately represent the various interests and negotiate in good faith to reach a consensus on a proposed rule; (3) whether the negotiation process will not unreasonably delay issuance of the rule; (4) whether the agency has adequate resources to support the negotiating committee; and (5) whether the agency -- to the maximum extent consistent with its legal obligations -- will use a committee consensus as the basis for a proposed rule. These criteria are based on recommendations of the Administrative Conference and actual agency experience using the process.[39]

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[38] *See* 5 U.S.C. § 583.

[39] *See* Recommendations No. 82-4, 85-5, "Procedures for Negotiating Regulations," 1 C.F.R. §§305.82-4, 305.85-5.

In addition, there should be a number of diverse issues that participants can rank according to their own priorities, so that there will be room for compromise on some of the issues as an agreement is sought. However, it is essential that the issues to be negotiated not require compromise of principles so fundamental to the parties that meaningful negotiations are impossible. Parties must indicate a willingness to negotiate in good faith, and no single interest should be able to dominate the negotiations.

The goal of the committee is to reach consensus on a draft rule. The word "consensus" is usually understood in this context to mean that each interest represented, including the agency, concurs in the result, unless all members of the committee agree at the outset to a different meaning. Negotiators try to reach a consensus through a process of evaluating their own priorities and making tradeoffs to achieve an acceptable outcome on the issues of greatest importance to them. The existence of a deadline for completing negotiations, whether imposed by statute, by the agency, or by other circumstances, has been found to impart a degree of urgency that can aid the negotiators in reaching a consensus on a proposed rule.

If a consensus is achieved by the committee, the agency ordinarily would publish the draft rule based on that consensus in a notice of proposed rulemaking -- and the agency would have committed itself in advance to doing so. Such a commitment is not an abdication of the agency's statutory responsibility, for there would not be a consensus without the agency's concurrence in the committee's proposed rule.[40] Even negotiations that result in less than full consensus on a draft rule can still be very useful to the agency by narrowing the issues in dispute, identifying information necessary to resolve issues, ranking priorities, and finding potentially acceptable solutions.

Negotiated rulemaking should be viewed as a supplement to the rulemaking provisions of the Administrative Procedure Act. This means that the negotiation sessions generally take place prior to issuance of the notice and the opportunity for the public to comment on a proposed rule that are required by the Act. In some instances, negotiations may be appropriate at a later stage of the proceeding.

The Negotiated Rulemaking Act was intended to clarify agency authority to use the process. The Act establishes basic public notice requirements, including provision of an opportunity for members of the public who believe they are inadequately represented on a negotiating committee to apply for membership or better representation. The Act also clarifies the applicability of the Federal Advisory Committee to reg-neg.[41]

For a detailed discussion of all aspects of negotiated rulemaking, the reader is referred to the *Negotiated Rulemaking Sourcebook*, published in 1990 by the Administrative Conference. The *Sourcebook* contains a step-by-step guide for the conduct of reg-neg proceedings, with samples of necessary *Federal Register* notices and other relevant documents. The volume also contains a number of analytical articles that examine the experiences of several federal agencies that have used the process, including EPA, OSHA and the Department of Transportation.

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[40] Nor would such an agreement undercut the agency's authority to make changes at the final rule stage. *Natural Resources Defense Council v. EPA*, 859 F.2d 156, 194-95 (D.C. Cir. 1988).

[41] *See* 5 U.S.C. §§ 584, 585. *See also* Part II, Ch. 3(D), (E), *supra*.

PART III: INFORMAL RULEMAKING IN PRACTICE

CHAPTER 2

REGULATORY ANALYSIS AND REVIEW

Regulatory analysis and review requirements derive from several different statutes and executive orders, which are discussed in Parts I and II. This Chapter summarizes their practical effects for agency rulemakers.

For "major" rules subject to Executive Order No. 12,291, rules likely to have significant economic impact on small businesses or containing information collection requirements, and rules implicating certain other policy interests, an agency must be prepared, when it authorizes publication of a notice of proposed rulemaking (NPRM), to explain and provide support for its choice of a preferred regulatory approach to a problem. Where such analyses are required, an initial or preliminary report must generally be prepared in conjunction with the NPRM, and a final report, responding to comments on the earlier report, must be prepared with the final rule.[1]

Executive Order No. 12,291 requires an initial analysis for "major" rules that evaluates the potential costs and benefits of the proposed rule. It also requires a description of alternative approaches that could substantially achieve the same regulatory goal at lower cost and a brief explanation of the legal reasons why such alternatives could not be adopted.[2] The Paperwork Reduction Act[3] requires an agency to justify the burdens imposed by information collection requirements. The Regulatory Flexibility Act[4] requires the agency's initial analysis accompanying the NPRM to describe in detail the expected impact of the proposed rule on small entities and to evaluate significant alternatives to the proposed rule. In addition, executive orders on federalism, the just compensation clause, and the family may require analysis of a rulemaking's impacts in particular areas.[5]

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[1] For discussion of the requirements associated with the final rule, see Part III, Ch. 7.

For each of these statutes and executive orders, this chapter will discuss (1) which types of rules are subject to the analysis requirements; (2) generally what are the applicable requirements; and (3) what is the review process.

A. Executive Order No. 12,291

Executive Order No. 12,291 is intended to minimize duplication and conflict in federal regulation, and to ensure that any promulgated regulation involves the least net cost.[6] The order sets forth certain policy requirements which, "to the extent permitted by law," a federal agency[7] is required to follow in promulgating new regulations, reviewing existing regulations, and offering legislative proposals.[8]

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[2] Exec. Order No. 12,291, § 3(d)(4), set out as a note to 5 U.S.C. § 601.

[3] 44 U.S.C. §§ 3501-20.

[4] 5 U.S.C. §§ 601-12, also discussed *supra*, Part II, Ch. 3(A).

[5] *See* subs. D, *infra*.

[6] Exec. Order No. 12,291 is also discussed *supra*, Part I(D)(1).

[7] The order has been applied only to executive departments and agencies and not to independent agencies. The president's authority over independent agencies has been frequently debated. *See* Part I(D)(2), *supra*.

1. *Coverage*

Executive Order No. 12,291 requires executive branch agencies to prepare and send to the Office of Management and Budget (OMB) a preliminary regulatory impact analysis for all "major" rules 60 days prior to publication of the NPRM, unless the rules are covered by an exemption in section 8 of the order.[9] A "major" rule is one that is likely to result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, or "significant adverse effects" on competition, employment, or other aspects of the economy.[10] The exemptions cover regulations (1) that respond to emergency situations (although deferred compliance is required); (2) for which consideration under the order would conflict with deadlines imposed by statute or court order; or (3) that are exempted from any or all of the order's requirements by the Director of OMB.[11]

An agency makes the initial determination whether the proposed rule is "major," but the OMB Director is empowered to order that a rule be treated as a major rule and to require that any set of related rules be considered together as a single major rule.[12] The agency is not required to prepare an impact analysis for non-major rules, but these rules must be consistent with the principles of Executive Order No. 12,291, and proposed non-major rules must be transmitted to OMB for review at least 10 days prior to publication.[13] According to OMB, many agencies also perform an initial analysis of the economic impact of non-major rules if the agency believes the rule will have a significant effect, or if the analysis will be useful in assessing the impact of the rule.[14]

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[8] Exec. Order No. 12,291, § 2.
[9] *Id.*, § 3(c).
[10] *Id.*, § 1(b).
[11] *Id.*, § 8.
[12] *Id.*, § 3(b).

OMB may exempt classes of regulations from the Executive Order's requirements, in addition to those explicitly exempt. By the end of 1989, OMB had granted twenty-nine exemptions, most during the initial years of the Executive Order, determining that the exempted regulations "as a class" were consistent with the goals and requirements of the Executive Order.[15] Those exemptions fall into four broad categories: (1) rules that are "essentially nonregulatory"; (2) rules delegating regulatory activity to the states; (3) rules largely affecting individual entities that do not involve "larger policy issues"; and (4) rules unlikely to involve "significant policy issues" for which even a brief delay could impose "significant costs."[16]

The Executive Order also requires agencies to publish twice a year an agenda of proposed regulations that the agency has issued or expects to issue.[17]

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[13] *Id.*, § 3(c)(3).

[14] OMB Annual Report for 1989 on Executive Order No. 12,291, *reprinted in* 1990-1991 *Regulatory Program of the United States Government* (hereafter 1990-1991 *Regulatory Program*), Appendix IV, at 624.

[15] *Id.* at 623, 634.

[16] *Id.* at 634, 648.

[17] *Id.*, §5. *See also* subs. (E), *infra*.

2. *Content of the Analysis*

Executive Order No. 12,291 sets out information that a Regulatory Impact Analysis (RIA) must contain: (1) a description of the rule's potential benefits and who will receive them; (2) a description of the potential costs and who will bear them; (3) a determination of the net benefit of the rule; and (4) a description of alternative approaches that could achieve substantially the same goal, and an explanation of why such alternatives could not be adopted.[18]

OMB has expanded on these requirements, focusing on what it considers to be important elements of the analysis.[19] First, OMB has stressed that there must be a statement of the need for the proposed rule. This should include a discussion of the market failure that makes a rule needed, and why other, non-federal alternatives (*e.g.*, workers' compensation schemes, or state or local action) are insufficient.[20] The RIA should examine alternative regulatory approaches, such as non-uniform application of standards or performance-oriented standards.[21] The RIA must also explain the rationale for selecting the regulatory choice being proposed, which ordinarily should be the one with the greatest net benefit.[22] Finally, the RIA should demonstrate that the proposed activity is within the agency's authority.[23]

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[18] Exec. Order No. 12,291, §3(d).

[19] "Regulatory Impact Analysis Guidance", Appendix V, 1990-1991 *Regulatory Program*, at 653. *See also id.* at 32-41.

[20] *Id.* at 653-55. Such analysis is required even where regulation is statutorily required. *Id.* at 34-35.

[21] *Id.* at 655-56.

[22] *Id.* at 665.

[23] *Id.*

Of importance is OMB's supplementary guidance on calculating benefits and costs.[24] OMB instructions state that an attempt should be made to quantify benefits in monetary terms "to the maximum extent possible."[25] To monetize benefits such as reductions in safety risks, which are not traded in the marketplace, OMB suggests that "willingness to pay" always provides the preferred measure of benefits,"[26] and discusses in some detail methods for calculating various types of benefits and costs. Several approaches for the valuation of reduction in fatality risks are also offered.[27] In addition, agencies are advised to make assumptions explicit[28] and to present sensitivity analysis (showing the effect of alternate assumptions on cost and benefits).[29] OMB also discusses discounting future costs and benefits to their present values,[30] and considering trade effects.[31]

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[24] *Id.* at 656-65

[25] *Id.* at 660.

[26] *Id.*

[27] *Id.* at 662. This topic was addressed by the Administrative Conference in Recommendation No. 88-7, "Valuation of Human Life in Regulatory Decisionmaking," 1 C.F.R. § 305.88-7. The Conference recommended that agencies "should disclose the dollar value per statistical life used" for determining whether compliance costs to reduce the risk to human life are justified. *Id.* ¶1. The Conference concluded that it would be useful if the agencies "would reveal publicly the processes through which they have determined the valuation of life incorporated in policy decisions," thus "provid[ing] useful clarification and exposition of the unavoidable trade-offs in regulating hazards," and permitting agency practice to be measured against valuation techniques used elsewhere. *Id.*, Preamble. The Recommendation is based on Gillette & Hopkins, *Federal Agency Valuations of Human Life*, 1988 ACUS Recommendations & Reports 367.

[28] 1990-1991 *Regulatory Program* at 659

[29] *Id.* at 658 ("Treatment of Risk and Uncertainty").

[30] *Id.* at 657 ("Discounting").

[31] *Id.* at 659.

The Administrative Conference addressed issues relating to regulatory analysis in its 1985 Recommendation, "Agency Procedures for Performing Regulatory Analysis of Rules."[32] Recommendation No. 85-2 contains advice on the use and limits of regulatory analysis and on integration of regulatory analysis into the agency rulemaking process. It stresses that the regulatory analysis process must be integrated into the agency's decisionmaking process from the beginning, and not "used to produce post hoc rationalizations for decisions already made."[33] The analysis should discuss its major assumptions, and explain why the agency selected a particular set of assumptions, inferences or models.[34]

3. *Review by OMB*

With limited exceptions, all executive branch agency proposed rules must be submitted to OMB for review under Executive Order No. 12,291. Independent regulatory agencies are exempt from review under Executive Order No. 12,291, but not from OMB review of information collection provisions in rules.[35] For major rules, the preliminary regulatory impact analysis must be transmitted to OMB 60 days before publication of the NPRM.[36] For other (*i.e.*, non-major) rules, the NPRM must be transmitted to OMB at least 10 days prior to Federal Register publication.[37] Within the 60- or 10-day period, respectively, OMB may request agency consultation on the preliminary regulatory impact analysis or NPRM, and if such a request is made, the agency must refrain from publishing its proposal until the review is concluded.[38]

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[32] Recommendation No. 85-2, 1 C.F.R. § 305.85-2. This Recommendation was based on McGarity, *The Role of Regulatory Analysis in Regulatory Decisionmaking*, 1985 ACUS Recommendations & Reports 107. *See also* McGarity, *Regulatory Analysis and Regulatory Reform*, 65 Tex. L. R. 1243 (1987).

[33] Recommendation No. 85-2 at ¶2.

[34] *Id.*, ¶4.

[35] *See* discussion of the Paperwork Reduction Act, *infra*, subs. (B).

[36] Exec. Order No. 12,291, § (3)(c)(2).

Regardless of whether an RIA is required, OMB will review the proposed rule to determine whether it is consistent with the standards of the Executive Order. These standards are set out in Section 2 of the Order:

> There must be sufficient information to support the need for and consequences of the rule;
>
> No regulatory action should be taken unless the potential benefits to society outweigh the costs;
>
> Regulatory objectives are to be chosen to maximize the benefits to society;
>
> The regulatory alternative that involves the least net cost to society is to be chosen;
>
> Regulatory priorities are to be set to maximize benefits to society, taking into account the condition of the industries regulated, the national economy, and contemplated future regulation.[39]

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[37] *Id.* at § 3(c)(3). As noted, *supra* text at n.14, some agencies prepare some type of impact analysis for non-major rules as well.

[38] *Id.* at § 3(f)(1). An agency, however, may proceed if regulatory review will delay promulgation of a rule beyond a statutory deadline. *See Environmental Defense Fund v. Thomas*, 627 F. Supp. 566 (D.D.C. 1986).

[39] Exec. Order No. 12,291, § 2.

As discussed in Part I,[40] the review process can be quite time-consuming.

B. The Paperwork Reduction Act

Enacted in 1980, and amended in 1986,[41] the Paperwork Reduction Act has as its main purposes to "minimize federal paperwork burden for individuals, small business and State and local government, . . . to minimize the cost of information collection to the Federal Government, . . . , and to maximize the usefulness" to the federal government of the information collected.[42] The Act statutorily established the Office of Information and Regulatory Affairs (OIRA) in OMB and assigned the agency responsibility for reviewing agency information collection requirements. The Act contains clearance procedures, which have been supplemented in detailed regulations issued by OMB.[43] The clearance requirements apply to agency information collections imposed through rulemaking as well as to other types of information collection; the requirements for the former are more detailed.[44]

1. *Coverage*

The Paperwork Reduction Act applies to rules that contain information collection provisions.[45] The Act requires the agency to justify to OMB the use of the information collection, and to show that it is the least burdensome possible, that it is not duplicative of other federal information collections, and that the collected information will have practical utility.[46] While the Act covers virtually all federal agencies, independent agencies may by majority vote overrule OMB's determinations.[47]

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[40] *See* Part I(D)(2), *supra*.

[41] The Act was scheduled to be reauthorized in 1990.

[42] 44 U.S.C. § 3501.

[43] 5 C.F.R. Part 1320.

[44] *Compare* 44 U.S.C. § 3504(h) *with* 44 U.S.C. § 3507(b).

[45] OMB's interpretation of the scope of "information collection requirements" has been restricted by the Supreme Court in *Dole v. United Steelworkers of America*, 110 S. Ct. 929 (1990), which invalidated OMB's reading of the term to include disclosures to third parties as well as to the government. *See* discussion of this case in Part II, Ch. 3(B)(3), *supra*.

2. *Content of the Analysis*

Proposed rules that contain information collection provisions must be submitted for review to OMB, along with supporting documents, no later than the date of publication of the NPRM in the Federal Register. As a practical matter, the deadlines for review under Executive Order No. 12,291 take precedence for all but independent regulatory agencies.[48] The agency must submit copies of documents to be used in the information collection, including the forms, instructions and informational documents.[49] The agency must also submit a statement containing, among other things, reasons for the information collection; who, how and for what the information will be used; how it will be collected; what efforts have been made to avoid duplication; costs of collection; and detailed information concerning the burden on those who would provide the information.[50] The agency must also indicate what steps it took to consult with interested agencies and members of the public to minimize burdens.[51] Moreover, the NPRM must notify the public that the rule has been sent to OMB and that the public may file comments on the information collection provisions with OMB.[52] The preamble to the NPRM must also include a brief statement concerning the need to collect the particular information, a description of the likely respondents, and an estimate of the annual recordkeeping and reporting burden.[53]

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[46] *See* 5 C.F.R. § 1320.4(b).

[47] 44 C.F.R. § 3507(c). For a more detailed discussion of the Act's coverage, including its limited exemptions, see Part II, Ch. 3(B).

[48] *See* Funk, *The Paperwork Reduction Act: Paperwork Reduction Meets Administrative Law*, 24 Harv. J. on Legis. 1, 85-93 (1987) (discussing interplay between Exec. Order No. 12,291 and Paperwork Reduction Act).

[49] OMB, Office of Information and Regulatory Affairs, Information Collection Review Handbook (1989) at 38.

3. *Review by OMB*

Under the Act, OMB has 60 days from the date the NPRM is published in the Federal Register to file comments on the information collection provisions.[54] The agency must demonstrate to OMB that it has taken every reasonable step to ensure that the information collection is the least burdensome necessary, that it is not duplicative of information otherwise accessible to the agency, and that the information has practical utility.[55]

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[50] *Id.* at 38-43.

[51] 5 C.F.R. §1320.4(a)(3).

[52] *Id.* at § 1320.13(a).

[53] *Id.* at § 1320.15. The total burden must also be disaggregated and set forth in terms of the estimated average burden hours per response, the proposed frequency of response, and the estimated number of likely respondents. *Id.*

[54] 44 U.S.C. § 3504(h)(2). OMB also has sixty days following publication of the final rule to approve or disapprove the final provisions. *Id.*, § 3504 (h)(4), (5).

[55] If OMB does comment on the information collection, the agency must explain, in conjunction with the final rule, how it has responded to OMB's comments. 44 U.S.C. § 3504(h)(3).

C. The Regulatory Flexibility Act

1. *Coverage*

The Regulatory Flexibility Act directs all agencies to give particular attention to the potential impact of regulation on small businesses and other small entities and requires consideration of regulatory alternatives that are less burdensome to small entities.[56] Under the Act, the agency must prepare an initial regulatory flexibility analysis if the proposed rule would have a "significant economic impact upon a substantial number of small entities."[57] The analysis requirement may be avoided if the head of the agency certifies in the NPRM that the proposed rule will not have such impact, and sends the certification and supporting statement of reasons to the Chief Counsel for Advocacy of the Small Business Administration.[58] The certification decision is not subject to judicial review.[59] If a regulatory flexibility analysis is required, the initial analysis or a summary must be published in the NPRM.[60]

2. *Content of the Analysis*

The Regulatory Flexibility Act requires that a regulatory flexibility analysis be submitted for review by the Chief Council for Advocacy of the Small Business Administration. The regulatory flexibility analysis is in some ways similar to the regulatory impact analysis required under Executive Order No.

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[56] The Regulatory Flexibility Act is discussed in more detail *supra*, Part II, Ch. 3(A).

[57] 5 U.S.C. § 603(c).

[58] *Id.* at § 605(b).

[59] *Id.* at § 611.

[60] *Id.* at § 603.

12,291. The initial analysis must include a description and estimate of the number of affected small entities, a description of the compliance requirements, and identification, to the extent practicable, of federal rules that may duplicate, overlap or conflict with the rule. It must also discuss significant alternatives which minimize economic impacts on small entities, including "tiering" (*i.e.*, non-uniform requirements that take account of small business concerns), use of performance standards, and exemptions.[61] The final analysis must respond to comments, and explain why each significant alternative was rejected.[62]

3. *Review by the Small Business Administration*

The Chief Counsel for Advocacy's authority is limited to reviewing the analyses, and filing comments in the rulemaking; he cannot prevent the promulgation of a rule. The Regulatory Flexibility Act, however, requires at least annual reporting on agency compliance with the Act to both the President and Congress, and the Chief Counsel is specifically authorized to appear as *amicus curiae* ("friend of the court") in actions brought to review a final agency rule.[63]

D. Other Executive Orders

Other executive orders require analysis of particular regulations. These orders are relevant only to certain regulatory topics, and cover only executive departments and agencies. There are no specific time frames associated with OMB review under these three executive orders.

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[61] *Id.* at § 603(b),(c). The RIA also requires this information; the two can often be consolidated. See subs. (E), *infra*; 1990-1991 *Regulatory Program* at 655.

[62] *Id.*, § 604. The agency must make copies of the final analysis available to the public, but it is not required to publish the final analysis in the Federal Register. *Id.*

[63] 5 U.S.C. § 612.

Executive Order No. 12,612, "Federalism," requires consideration of issues of federalism by executive departments and agencies.[64] Its purpose is "to ensure that the principles of federalism established by the Framers [of the Constitution] guide the Executive departments and agencies in the formulation and implementation of policies."[65] Under the Order, the head of each executive department or agency is required to appoint an official who is responsible for the order's implementation and will prepare a "Federalism Assessment" for all proposed policies with "sufficient federalism implications."[66] Among other things, this Order contains direction to the agencies that they not construe a statute to be preemptive of state regulations unless the federal statute contains "an express preemption provision" or other "firm and palpable evidence."[67] OMB is made responsible for coordinating and reviewing agency actions so that they are consistent with the requirements of the Executive Order.[68]

Executive Order No. 12,630, "Governmental Actions and Interference with Constitutionally-Protected Property Rights," requires agencies to limit interference with private property rights protected under the fifth amendment to the Constitution.[69] The Order requires agencies to consider certain criteria when considering policies with takings implications,[70] and to include analysis of the impact of proposed regulations on such property rights in its submissions to OMB.[71] The Order is not applicable to independent regulatory agencies.

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[64] Exec. Order No. 12,612 (Oct. 26, 1987), 3 C.F.R. 252 (1987 Compilation).

[65] *Id.*, Preamble.

[66] *Id.*, § 6(a) and (b).

[67] *Id.*, § 4.

[68] *Id.*, § 7. The OMB review is to take place "to the extent permitted by law" and in connection with its monitoring activity under Executive Orders No. 12,291 and 12,498 and OMB Circular No. A-19.

Executive Order No. 12,606, "The Family," requires that agencies assess the impact of regulations on the family, and lists a number of criteria to be considered.[72] OMB is required, "to the extent permitted by law," to ensure that the policies set forth in the order are applied by covered agencies.[73]

E. Coordinating Analysis Requirements

Both the initial regulatory flexibility analysis and the preliminary regulatory impact analysis involve specific calculation or assessment of the economic impact of the proposed rule, as well as analysis of alternative regulatory approaches to addressing the problem. This kind of analysis requires that the agency have both a thorough understanding of the nature of the problem and data that can be used to estimate the effects of alternative courses of action. Therefore, where these requirements apply, agencies must allocate relatively large amounts of resources to preparating the NPRM and supporting documents.[74]

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[69] Exec. Order No. 12,630 (March 15, 1988), 3 C.F.R. 554 (1988 Compilation). The Department of Justice has issued guidelines for the Order: "Attorney General's Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" (June 30, 1988). Some agencies have their own supplemental guidelines, which must be approved by the Department of Justice.

[70] Exec. Order No. 12,630 at § 4

[71] *Id.* at § 5.

[72] Exec. Order No. 12,606 (Sept. 2, 1987), 3 C.F.R. 241 (1987 compilation).

[73] *Id.*, § 2(b).

The contents of the various required regulatory analyses may overlap sufficiently to permit collapsing them into a single document, or incorporating by reference to minimize redundancy. The Regulatory Flexibility Act specifically provides that agencies may perform regulatory flexibility analyses in conjunction with or as a part of any other analysis required by law, so long as the analysis satisfies the Act's requirements.[75] Similarly, Executive Order No. 12,291 states that the regulatory impact analysis may be combined with any regulatory flexibility analysis.[76] The Council on Environmental Quality's (CEQ's) regulations governing agency preparation of environmental impact statements (EIS) require that any cost-benefit analysis being considered for a proposed action "be incorporated by reference or appended to the [EIS] as an aid in evaluating the environmental consequences."[77] Paperwork Reduction Act requirements are also to be coordinated with review under Executive Order No. 12,291.[78]

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[74] For a in-depth discussion of agencies' regulatory analysis activities, see McGarity, *The Role of Regulatory Analysis in Regulatory Decisionmaking*, 1985 ACUS Recommendations & Reports 107. An unpublished section of this report, which describes in great detail the activities of certain agencies, is on file with the Office of the Chairman, Administrative Conference of the United States.

[75] 5 U.S.C. § 605(a).

[76] Exec. Order No. 12,291, ¶ 3(a).

[77] 40 C.F.R. § 1502.23. *See* Part II, Ch. 3(C), *supra*, for a brief discussion of EIS requirements.

[78] Exec. Order No. 12,291 § 6(b). Other executive orders similarly contemplate that agency analyses under those orders be incorporated with existing submissions to OMB. *See, e.g.*, Executive Order No. 12,630, "Government Actions and

If a proposed rule is subject to all these requirements, it would generally make sense to make the regulatory flexibility analysis, as well as any required paperwork burden analysis, parts of the regulatory impact analysis required by Executive Order No. 12,291. However, where an environmental impact statement (EIS) has been prepared, it would ordinarily be separate, or at least severable, from the regulatory impact analysis, even though the substance of each may overlap. This is because CEQ's regulations for preparing and circulating an EIS are quite specific and differ from the requirements for regulatory impact analysis.[79] Agencies may, however, include the EIS as an appendix to the regulatory impact statement.

The regulatory agendas required by Executive Order No. 12,291 and the Regulatory Flexibility Act are intended to be coordinated.[80] In fact, the two agendas are published together, as the Unified Agenda of Federal Regulations, under the aegis of the Regulatory Information Service Center.[81]

The rulemaking staff can refer to several sources for guidance on the substance of or criteria for completing the various analyses. The staff preparing a regulatory flexibility analysis may refer to a guide to the Regulatory Flexibility Act prepared for the Administrative Conference by Professor Paul

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Interference with Constitutionally Protected Property Rights," *supra* n. 69, at ¶ 5(b).

[79] *See* 40 C.F.R. §§ 1502.7, 1502.10, 1502.11 (page limit and format), 40 C.F.R. Part 1503 (opportunity to comment on environmental impact statements).

[80] *See* Exec. Order No. 12,291, §5.

[81] *See, e.g.*, 55 Fed. Reg. 15902 (1990) (April 1990 Unified Agenda) The Unified Agenda also incorporates the publication requirment for certain information relating to procurement regulations. *Id.*; Office of Federal Procurement Policy Act Amendments, 102 Stat. 4055, 41 U.S.C. § 402.

Verkuil.[82] OMB has issued guidance on the Paperwork Reduction Act.[83]

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[82] Verkuil, *A Critical Guide to the Regulatory Flexibility Act*, 1982 Duke L.J. 213.

[83] OMB, OIRA Information Collection Review Handbook (January 1989).

PART III: INFORMAL RULEMAKING IN PRACTICE

CHAPTER 3

THE NOTICE OF PROPOSED RULEMAKING

Issues relating to the notice of proposed rulemaking (NPRM) itself are covered in this section. The adequacy of the NPRM, discussed in this chapter, is closely related to the question whether the public was afforded a meaningful opportunity to participate in the rulemaking. The public's right to participate in the rulemaking proceedings, which is triggered by the publication of the NPRM, is discussed in the next chapter.[1]

A. Publication Requirements

For informal rulemaking not otherwise exempt from the APA's requirements, the APA requires that "general notice of proposed rulemaking shall be published in the Federal Register."[2] Publication in the Federal Register is referred to as "constructive notice," and is deemed legally sufficient to give affected persons notice of the NPRM's contents. Failure to publish a Federal Register notice of a proposed rule may result in the court setting aside the rule or remanding it to the agency for further proceedings.[3] The APA does provide, however, that

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[1] *See infra*, Part III, Ch. 4, "Public Participation."

[2] 5 U.S.C. § 553(b). An agency's enabling statute or the statute authorizing the rulemaking may have other requirements that must be considered.

[3] *See, e.g., PPG Industries Inc. v. Costle*, 659 F.2d 1239, 1249-51 (D.C. Cir. 1981). The rule may also be set aside where the NPRM is published in the Federal Register but its contents

Federal Register notice is not required if persons subject to the rule "are named and either personally served or otherwise have actual notice [of the rulemaking] in accordance with law."[4]

The prudent rulemaking staff should, however, view the "actual notice" substitute for the Federal Register notice with caution. Although there may be cases where other forms of notice are equal to or even superior to Federal Register notice, there simply is too much at stake in most rulemakings not also to publish an NPRM in the Federal Register.[5] Where interested persons can be readily identified, and more effective notice can be given by means other than the Federal Register,[6] many agencies both publish the proposal in the Federal Register and utilize other means of notice to better inform the affected public of the rulemaking.

The rulemaking staff should thus consider the advantages of giving notice of the rulemaking in addition to that provided in the Federal Register.[7] General notice may be accomplished by

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are determined to be inadequate to afford a meaningful opportunity for comment on the issues in the rulemaking. *See* discussion *infra*, subs. (D), (E).

[4] 5 U.S.C. § 553(b).

[5] The APA's "actual notice" provision may aid agencies defending rules in court, if the party challenging the rule had actual notice of an issue but, nevertheless, claims the Federal Register notice was inadequate. *See, e.g., Water Transport Ass'n v. ICC*, 684 F.2d 81, 84-85 (D.C. Cir. 1982); *Lloyd Noland Hospital & Clinic v. Heckler*, 762 F.2d 1561, 1565-66 (11 Cir. 1985). But the provision of "actual notice" may be of little help where the agency fails to publish any NPRM in the Federal Register. *See, e.g., Rodway v. Dep't of Agriculture*, 514 F.2d 809, 815 (D.C. Cir. 1975).

[6] Proceedings to establish utility rates fall in this category. A combination of personal service, circulation with utility bills, posting, etc., might give notice of the proceeding to all affected persons.

[7] See ACUS Recommendation No. 71-6, "Public Participation in Administrative Hearings," 1 C.F.R. § 305.71-6, ¶¶ A(1), E.

means such as press releases to general, trade, or other specialized publications, and notices to clearinghouse services and loose-leaf reporter services. The rulemaking staff also may "target" notice to persons most likely to be affected by the rule or to persons likely to have information needed to develop the rule. For example, notice may be sent to relevant trade associations or other membership organizations. The staff may also give notice through paid advertisements in the media or directly to individuals or groups concerned with the subject matter of the rule.

B. Contents of the Notice of Proposed Rulemaking

Section 553 of APA provides that the NPRM must state the "time, place, and nature" of the public proceedings.[8] The generality of this requirement may stem from the fact that section 553's notice provision applies both to formal rulemaking (where an oral hearing with cross-examination is required) and to notice-and-comment rulemaking. In the context of notice-and-comment rulemaking, this language requires the agency to specify the type of rule involved; the time during which the agency will receive written comments on the proposal; and instructions regarding the manner of filing comments.[9]

The APA does not specify a minimum period for comment. A common misconception is that the APA prescribes a 30-day minimum comment period, a belief that may derive from the

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[8] 5 U.S.C. § 553(b)(1).

[9] The rules of the Administrative Committee of the Federal Register contain more specific requirements for the contents of the "formal" portions of the Federal Register notice. *See* discussion *infra*, subs. (C).

APA's requirement that final rules be published thirty days prior to their effective date.[10] A reasonable time should be allowed for comment, with "reasonableness" judged in relation to the particular facts of each rulemaking.

As a practical matter, many agencies provide 60 more days for complex or controversial rules.[11] Even when a shorter comment period is allowed, the agency may extend the period for comment where a legitimate request for extension has been received. In such a case, of course, notice of the extension should be published in the Federal Register to give all members of the public an equal opportunity to comment. Some enabling statutes expressly provide for a specific minimal period for public comment.[12] Agencies also have the discretion to accept late comments.

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[10] 5 U.S.C. § 553(d). The 30-day period following publication is not intended to provide an opportunity for comment; it is a grace period for coming into compliance with the rule, and, consequently, may be omitted when the rule grants an exemption or relieves a restriction, § 553(d)(1). *See* discussion *supra*, Part II, Ch. 1(D)(4)(d).

[11] *See, e.g.*, Federal Highway Administration, Motor Carrier Safety Standards: Controlled Substances, Notice of Proposed Rulemaking, 53 Fed. Reg. 22,268 (1988) (90-day comment period). The NPRM also stated that the agency was considering holding a public hearing on the proposal; the hearing, if held, would be announced later in Federal Register.

[12] *See, e.g.*, Safe Water Drinking Act, 42 U.S.C. §300g-1(b)(2)(B); *cf.* 42 U.S.C. § 1395hh(b)(1) (requiring minimum 60-day comment period for certain rules in the Medicare program). *See also* 20 U.S.C. 1232(b) (requiring 30-day comment period for Dep't of Education regulations).

The Administrative Conference, in a 1982 statement of views on legislation then pending in Congress that would have established a minimum 60-day comment period for notices of proposed rulemaking, stated that it had "no objection to enactment . . . [of the minimum comment period provision] . . . provided that the 'good cause' exception in section 553(b) is retained." Views of the Administrative Conference on Proposals Pending in Congress to Amend the Informal Rulemaking Provisions of the APA, 1 C.F.R. § 310.7. In the Conference's

The Notice of Proposed Rulemaking

Section 553 requires the notice of proposed rulemaking to contain a "reference to the legal authority under which the rule is proposed."[13] Although this requirement is fairly straightforward, it has occasionally been an issue on judicial review, and courts have invalidated rules for failure to comply with it.[14]

The APA also requires the NPRM to include "either the terms or substance of the proposed rule or a description of the subjects and issues involved."[15] The Attorney General's Manual on the APA recommended that agencies only include in the proposal a description of the subjects and issues of the rulemaking, rather than the terms of a proposed rule, if "publication . . . in full would unduly burden the Federal Register or would in fact be less informative to the public."[16] Today, however, most agencies publish the text of the proposed rule when commencing rulemaking, and some enabling statutes expressly require that the agency do so.[17] The heightened scrutiny given agency rules by courts, as well as the additional analysis required by executive orders, NEPA, and the

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view, an agency should be able to dispense partially or fully even with this longer minimum period for comment when the agency determines that "notice and public procedure . . . are impracticable, unnecessary, or contrary to the public interest."

[13] 5 U.S.C. § 553(b)(2).

[14] *See, e.g., National Tour Brokers Ass'n v. U.S.*, 591 F.2d 896, 900 (D.C. Cir. 1978).

[15] 5 U.S.C. § 553(b)(3).

[16] Attorney General's Manual on the APA at 29 (1947), *reprinted in* ACUS Federal Administrative Procedure Sourcebook.

[17] *See, e.g.*, Federal Trade Commisssion Act, 15 U.S.C. 57a(b)(1)(A) (agency must "publish a notice of proposed rulemaking including with particularity the text of the rule, including any alternatives which the Commission proposes to promulgate; and the reasons for the proposed rule").

Regulatory Flexibility Act, are incentives for prior agency consideration and publication of specific proposals.[18] Specific proposals help focus public comment, and that, in turn, assists reviewing courts in deciding whether interested persons were given a meaningful opportunity to participate in the rulemaking.

The NPRM must also describe compliance with the Regulatory Flexibility Act, the Paperwork Reduction Act, and Executive Order No. 12,291.[19] For example, the preamble of a regulation containing information collection requirements must notify the public that the proposal was sent to OMB for review, and that the public may file comments with OMB.[20] Under Executive Order No. 12,291, a rule's preamble must either explain why it is not a major rule, or if it is, summarize the regulatory impact analysis.[21]

C. Federal Register Requirements

In 1934, Congress enacted the Federal Register Act, establishing a uniform system for the handling of federal agency regulations through the filing of documents with the Office of the Federal Register, placement of documents for public inspection, publication of documents in the Federal Register, and codification of rules in the Code of Federal

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[18] *See* Part III, Ch. 2; Part IV, Ch. 2. Advance notices of proposed rulemaking, discussed *supra*, Part III, Ch. 1(B)(1), may further assist the agency in preparing a specific proposal for publication.

[19] For a description of the scope of these requirements, *see* Part III, Ch. 2, *supra*.

[20] 44 U.S.C. § 3507(a).

[21] Exec. Order No. 12,291 §3(g), *reprinted in* 5 U.S.C. § 601 note.

Regulations.[22] The Administrative Committee of the Federal Register has issued regulations under the statute:[23] Subchapter E of its rules deals particularly with the preparation, transmittal and processing of documents.[24]

Particularly relevant is section 18.12 in 1 CFR, entitled "Preamble requirements", which sets forth minimum requirements for the form and substance of agency preambles that are to be published in the Federal Register. Agency staff should pay particular attention to these requirements, since the Director of the Office of the Federal Register may return to the issuing agency any document submitted for publication in the Federal Register that does not comply with the publication requirements.[25] One general requirement is that every proposed or final rule must include "a preamble which will inform the reader, who is not an expert in the subject area, of the basis and purpose for the rule or proposal."[26] Additionally, the preamble must follow a set format, or the Office of the Federal Register will not print the rule document.[27] The Office of the Federal Register's Document Drafting Handbook[28] provides detailed instructions for drafting rules and proposed

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[22] 44 U.S.C. § 1501 *et seq.* The Federal Register Act is also discussed *supra*, Part II, Ch. 3(F).

[23] 1 C.F.R. Chapter I, encompassing Parts 1-22. The Administrative Committee of the Federal Register recently amended and consolidated these rules. 54 Fed. Reg. 9670 (1989).

[24] 1 C.F.R. Parts 15-22.

[25] 1 C.F.R. § 2.4(b).

[26] 1 C.F.R. § 18.12(a).

[27] *See* 1 C.F.R. § 18.12(b).

[28] National Archives and Records Adm., Office of the Federal Register, Document Drafting Handbook (1986).

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rules.[29] The Federal Register staff also may be consulted for additional assistance.

An agency wishing to incorporate material into a rule by reference must also comply with relevant Federal Register requirements.[30] Generally, any published data, criteria, standards, and similar material may be incorporated by reference into a rule if it is reasonably available to and usable by the class of persons affected by the agency's rule and it is not produced by the agency.[31] When incorporating documents by reference, however, agencies should be mindful of the effect the incorporation has on the intelligibility of the notice. In *PPG Industries, Inc. v. Costle*,[32] EPA referenced internal agency guidelines on acceptable test methods for assuring air quality in a footnote in the NPRM, but did not indicate that the guidelines were intended to be legally incorporated by reference.[33] The referenced guidelines were intended to change the monitoring requirements for regulated industries. When EPA sought to enforce the guidelines, the reviewing court held them invalid because the agency had not given the public sufficient notice and opportunity to comment on this aspect of the NPRM, and further, EPA had failed to give adequate notice in the final rule of the change, since it had neither published the guidelines nor formally incorporated them by reference.[34]

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[29] The publication is available through the Government Printing Office.

[30] The requirements are published at 1 C.F.R. Part 51. *See also* Document Drafting Handbook, *supra* n. 28, at 39; *Appalachian Power Co. v. Train*, 566 F.2d 451 (4th Cir. 1977).

[31] 1 C.F.R. § 51.7.

[32] 659 F.2d 1239 (D.C. Cir. 1981).

[33] It should be noted that the Federal Register usually will not approve agency incorporation by reference of a publication of the same agency. 1 C.F.R. § 51.7(b).

D. Adequacy of the Notice

The notice-and-comment procedures of the APA are intended to encourage public participation in the administrative process, to help educate the agency, and thus produce more informed agency decisionmaking.[35] In order to obtain "meaningful" participation from the public, it has been consistently held that the NPRM must "fairly apprise interested persons" of the issues in the rulemaking.[36] If the final rule differs to such a great extent from the agency's proposal that it can be said that the public was not apprised of the issues in the proceeding, the court may vacate the final rule for inadequate notice.

This does not mean that the agency may not alter the proposal in its final rule. Indeed, the final rule "must so differ [from the proposal] when the record evidence warrants the change."[37] In the oft-quoted statement of the District of Columbia Circuit:

> A contrary rule [that the final rule may not modify the proposal] would lead to the absurdity that in rule-making under the APA the agency can learn from the comments on the proposals

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[34] 659 F.2d at 1249-50.

[35] *Chocolate Mfrs. Ass'n v. Block*, 755 F.2d 1098, 1103 (4th Cir. 1985). *See* discussion *infra*, Part III, Ch. 4.

[36] *United Steelworkers v. Marshall*, 647 F.2d 1189, 1221 (D.C. Cir. 1980), quoting *American Iron and Steel Institute v. EPA*, 568 F.2d 284, 293 (3d Cir. 1977).

[37] *United Steelworkers*, *supra* n. 36, 647 F.2d at 1221.

> only at the peril of starting a new procedural round of commentary.[38]

However, an agency does not have complete discretion to change radically a proposed rule simply in response to adverse comments.[39] The issue thus becomes whether the notice adequately alerted the interested parties of the possibility of the changes which were eventually adopted.

A variety of tests have been devised to help the courts decide whether notice in the NPRM was adequate. The most frequently applied test is whether the final rule was a "logical outgrowth" of the proposal and comments.[40] Subsequent court decisions have described this test as a "verbal formula" which "only take[s] us so far," and have attempted to refine it.[41] In a recent case, *American Medical Association v. United States*,[42] the Seventh Circuit enunciated a number of general principles governing the adequacy of a notice of proposed rulemaking. The court said:

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[38] *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 632, n. 51 (D.C. Cir. (1973)).

[39] *Chocolate Mfrs Ass'n, supra* n. 35, 755 F.2d at 1104.

[40] *See South Terminal Corp. v. EPA*, 504 F.2d 646, 659 (1st Cir. 1974) for an early statement of the "logical outgrowth" test, and *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983), for a more recent statement. In the latter case, the court said that the task of the court is fundamentally one of balancing, on the one hand, the advantages of additional comment, improving the quality of rules, fairness, and facilitating judicial review, against, on the other hand, the burden on "the public interest in expedition and finality." *Id.* at 547. *See also City of Stoughton v. EPA*, 858 F.2d 747, 751, 753 (D.C. Cir. 1988); *Action Alliance of Sr. Citizens v. Bowen*, 846 F.2d 1449, 1455 (D.C. Cir. 1988); *NRDC v. Thomas*, 838 F.2d 1224, 1242 (D.C. Cir. 1988). For a discussion on whether the final rule may be based on the public comments rather than the proposed rule, *see* text below at nn. 45-50.

[41] *United Steelworkers, supra* n. 36, 647 F.2d at 1121. The District of Columbia Circuit continues to use the "logical outgrowth" test.

[42] 887 F.2d 760 (7th Cir. 1989).

> That an agency changes its approach to the difficult problems it must address does not signify the failure of the administrative process. Instead, an agency's change of course, so long as generally consistent with the tenor of its original proposals, indicates that the agency treats the notice-and-comment process seriously, and is willing to modify its position where the public's reaction persuades the agency that its initial regulatory suggestions were flawed.
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> Of course, in this context the enunciation of general legal principles is not especially helpful. The adequacy of notice in any case must be determined by a close examination of the facts of the particular proceeding which produced a challenged rule. However, without reciting in detail the facts of other cases, we note that courts have upheld final rules which differed from proposals in the following significant respects: outright reversal of the agency's initial position; elimination of compliance options contained in an NPR; collapsing, or further subdividing, distinct categories of regulated entities established in a proposed rule; exempting certain entities from the coverage of final rules; or altering the method of calculating or measuring a quantity relevant to a party's obligations under the rule.
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> On the other hand, a rule will be invalidated if no notice was given of an issue addressed by the final rules. Moreover, courts have held on numerous occasions that notice is inadequate where an issue was only addressed in the most general terms in the initial proposal, or where a final rule changes a pre-existing agency practice which was only mentioned in an NPR in order to

> place unrelated changes in the overall regulatory scheme into their proper context.
>
> The crucial issue, then, is whether parties affected by a final rule were put on notice that "their interests [were] 'at stake'", in other words, the relevant inquiry is whether or not potential commentators would have known that an issue in which they were interested was "on the table" and was to be addressed by a final rule.[43]

Judged by these standards, the court held that the American Medical Association had received adequate notice of the Internal Revenue Service's rule on allocation of membership dues. The court concluded that the rule's final approach, "while substantially different from the NPR," was a logical outgrowth of the original proposal, since the final rule dealt with the identical issue as the NPRM, was not a "wholly new approach" and was contained in the proposed version. Thus, the court ruled, "all aspects of the final rule were available to the public for comment."[44]

In determining the adequacy of notice, some courts have attempted to determine whether changes in the final rule were in fact made in response to comments received during the rulemaking. In *United Steelworkers of America v. Schuylkill Metal Corp.*,[45] the Fifth Circuit rejected a claim that OSHA's proposal did not adequately alert the public that the scope of medical removal benefits under the OSHA occupational health standard for lead was at issue in the rulemaking. Noting that public comments received by the agency expressly raised the medical removal issue, the court concluded that "it was readily apparent to interested parties that the scope of . . . [removal] benefits was in dispute" and therefore these comments provided "additional support for the broad, final rule."[46]

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[43] *Id.* at 767-68 (footnotes omitted).

[44] *Id.* at 769. *Cf. Chocolate Mfrs. Ass'n v. Block*, *supra* n. 35, 755 F.2d at 1105 (court cast criteria as (1) whether the final rule was "in character with the original scheme," (2) whether the final rule materially altered the issues in the rulemaking, and (3) whether the final rule "substantially departs from the terms or substance of the proposed rule.")

[45] 828 F.2d 314 (5th Cir. 1987).

Other courts have refused to use public comments on an issue as the basis for a finding that the notice was adequate. In *AFL-CIO v. Donovan*,[47] a case involving the Department of Labor's revision of its regulations under the Service Contract Act, the court said: "Neither can we properly attribute notice to the other appellants on the basis of an assumption that they would have monitored the submission of comments."[48] The court relied on an earlier statement by the same court that "notice necessarily must come -- if at all -- from the agency,"[49] and vacated a portion of the rules as violative of APA notice-and-comment requirements.[50]

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[46] *Id.* at 318. The court of appeals also found that the NPRM "more than adequately sufficed to apprise fairly an interested party that there was an issue regarding the breadth of . . . [medical] benefits." *Id.* The court added that it was not necessary to apprise parties "such as these sophisticated industry members," who had challenged the standard a number of times to "spell out with particularity" the proposed meaning of the medical benefits. *Id.* In *Associated Builders and Contractors v. Brock*, 862 F.2d 63, 67 (3d Cir. 1988), the court relied in part on an ANPR in holding that the proposal provided adequate notice of the agency's consideration of the issue of industry-wide coverage of hazard communication standard. *See also Rybachek v. EPA*, 904 F.2d 1276, 1288 (9th Cir. 1990).

[47] 757 F.2d 330 (D.C. Cir. 1985).

[48] *Id.* at 340.

[49] *Id.*, quoting *Small Refiner Lead Phase-Down Task Force*, *supra* n. 40, 705 F.2d at 549.

[50] The court stated that the principle that comments should not be relied on to provide notice was "particularly appropriate" in that case, since only two comments had been received on the

Thus, the issue whether, and in what circumstances, a court will find agency notice to be adequate is a fact-driven inquiry. In some cases the courts have struggled to find, and have found, adequacy of notice;[51] in others, courts have vacated rules, because, as the court in *Chocolate Manufacturers Ass'n v. Block* stated, the notice "does not serve the policy underlying the notice requirement."[52] Because courts may be strict in insisting that notice be adequate, and because policy considerations strongly favor full and meaningful public participation, it is essential that agency officials, in drafting the NPRM and during the rulemaking proceeding, give special attention to the potential vulnerability of a final rule on adequacy-of-notice grounds.[53] In particular, the rulemaking

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issue in a rulemaking of "broad scope" in which some 1600 comments were received. *Id.* The court in this connection quoted *Wagner Electric Corp. v. Volpe*, 466 F.2d 1013, 1019 (3d Cir. 1972), which held that the fact that "some knowledgeable manufacturers" responded is not relevant since "others possibly not so knowledgeable" had a right to adequate notice. *Id. Cf. Edison Electric Institute v. OSHA*, 849 F.2d 611 (D.C. Cir. 1988) (party challenging adequacy of notice introduced in rulemaking record the record from another rulemaking which discussed disputed issue "at length"; court finds notice adequate).

See also Chocolate Mfrs. Ass'n v. Block, supra, n. 35; *Action Alliance of Sr. Citizens v. Bowen*, 846 F.2d 1449 (D.C. Cir. 1988) (applying the logical outgrowth test to OMB comments, and suggesting that additional notice and comment may not be required where it is potentially futile exercise; *but see* Wald, J. dissenting (material changes require notice and comment)).

[51] *See, e.g., United Steelworkers v. Marshall, supra n. 36.* In that case, OSHA had proposed a permissible exposure limit for lead of 100 micrograms; in its final rule it reduced the permissible level to 50 micrograms.

[52] *Supra* n. 35, 755 F.2d at 1107.

[53] As discussed *infra*, Part III, Ch. 7, the preamble to the final rule must carefully address discrepancies between the proposal in the NPRM and the final rule. A well-reasoned explanation of how the final rule derived from (or is the "logical outgrowth" of) the NPRM can be extremely useful if a rule is challenged.

staff must be aware of the importance of the wording of the proposed rule and the language of the preamble to the proposal. It must make as clear as possible which issues are "on the table."

While specific proposals are valuable in focusing comment, they may ultimately place the agency at a disadvantage, in that the proposal's very specificity might limit the options available in the final rule. On the other hand, although a generally-worded proposal may well avoid some of the restrictive effects of a too-specific proposal,[54] an agency must be careful that such a proposal is not so general that it affords inadequate notice of particular issues in the proceeding.

One way an agency can both set forth specific proposals in an NPRM and retain flexibility in fashioning the final rule is to include in the NPRM several alternatives that are under consideration. Thus, for example, the National Highway Traffic Safety Administration's proposed rule on passive restraints in automobiles, issued after remand from the Supreme Court,[55] contained several options that the agency was considering.[56] Similarly, EPA's NPRM for regulating benzene exposure under the Clean Air Act contained four alternative proposed rules, each containing significantly different permissible exposure levels.[57]

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[54] *See American Medical Ass'n v. U.S., supra* n. 42, 887 F.2d at 767.

[55] *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29 (1983).

[56] 48 Fed. Reg. 48,622 (1983). The proposal suggested a range of alternatives and proposed other actions that could be taken in conjunction with, or as a supplement to, those alternatives. The agency then held public meetings in three cities and received over 6000 comments on the NPRM.

A related approach would be for the agency, in addition to its specific proposal, to pose a series of questions going beyond the terms of the proposal on which it seeks comment. OSHA utilized this strategy in its proposed standard on ethylene oxide[58] and, as it developed, the major issue in the rulemaking -- whether a short term exposure limit should be established -- was raised not in the proposed rule itself but in one of the questions in the preamble.

This discussion suggests that the rulemaking staff should routinely give serious consideration to going beyond the minimum legal requirements in giving notice. A focused and well-explained NPRM can educate the public and generate more helpful information from interested persons. From a purely tactical viewpoint, it is desirable to find out earlier rather than later about views and information adverse to the agency's proposal.[59]

E. Agency Disclosure of Important Data or Information

The factual basis for agency rules frequently is subject to close judicial scrutiny. As discussed in more detail below, the more closely courts have reviewed the data supporting rules, the more sensitive they have become to the fact that meaningful comment on proposed rules can be precluded by the failure of agencies to disclose especially relevant information. In a leading early example, *Portland Cement Association v. Ruckelshaus*,[60] Judge Leventhal stated that:

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[57] EPA Proposed Rule and Notice of Public Hearing, National Emission Standards for Hazardous Air Pollutants, Benzene, 53 Fed. Reg. 28,496, 28,497 (1988). The agency took this approach in part because of the court of appeals decision on EPA's vinyl choloride standard, *Natural Resources Defense Council v. EPA*, 824 F.2d 1146 (D.C. Cir. 1987). The final rule, 54 Fed. Reg. 38,044 (1989), took pieces from each alternative. *Id.* at 38,045.

[58] 49 Fed. Reg. 25,734 (1984).

[59] For the Administrative Conference's views on notice considerations, *see generally* Recommendation No. 76-3, "Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking," 1 C.F.R. § 305.76-3, ¶ 1(c).

> [I]t is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data or data that [in] critical degree, is known only to the agency.[61]

and:

> In order that rule-making proceedings to determine standards be conducted in orderly fashion, information should generally be disclosed as to the basis of a proposed rule at the time of issuance. If this is not feasible, . . . information that is material to the subject at hand should be disclosed as it becomes available . . . .[62]

This development requiring agencies to disclose relevant information is described more fully later in the next Chapter,[63] but it is mentioned here because of its obvious implications for the contents of the agency's NPRM.[64]

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[60] 486 F.2d 375 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974).

[61] *Id.* at 393.

[62] *Id.* at 394.

[63] *Infra*, Part III, Ch. 4.

[64] The Conference has recommended public disclosure of relevant data in several contexts. *See* Recommendation No. 76-3, "Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking, 1 C.F.R. § 305.76-3, ¶ 1(c) (Conference advises agencies to consider including in the NPRM a summary of current agency attitudes toward critical issues in the proceeding, and a description of and the location of the data on which the agency relied in publishing the NPRM; it also suggests including a description of the scientific tests and other procedures used by the agency and the significance

F. A Second Cycle of Notice and Comment

A second round of notice and comment may be useful in a number of circumstances. It may well avoid agency vulnerability in court on the issue of the adequacy of the notice, especially where it appears during the course of the rulemaking that the final rule will materially differ from the proposal.[65] The Administrative Conference has recommended that agencies consider providing for two cycles of notice and comment where comments bring new issues to the attention of the agency, as well as for rulemakings where from the outset the agency anticipates that the issues will be unusually complex or where the first notice contains only a general description of the subject and issues.[66] Other circumstances that might support a second cycle include the availability of new studies or experiments while the rulemaking is in progress; supervening legal developments such as statutes, regulations or court decisions that significantly affect the rulemaking; or any other important change in the framework of agency analysis of the rulemaking. Agencies often resort to a second cycle of notice and comment in these types of situations, and courts have expressed their approval of the technique, and disapproval of its non-use.[67]

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the agency has attached to them). *See also* Recommendation No. 79-4, "Public Disclosure Concerning the Use of Cost-Benefit and Similar Analyses in Regulation," 1 C.F.R. § 305.79-4; Recommendation No. 88-7, "Valuation of Human Life in Regulatory Decisionmaking," 1 C.F.R. § 305.88-7.

[65] *See* Rochvarg, *Adequacy of Notice of Rulemaking Under the Federal Administrative Procedure Act - When Should A Second Round of Notice and Comment Be Provided*, 31 Am. U. L. Rev. 1 (1981).

[66] Recommendation No. 76-3, *supra* n. 64, at ¶1(a), (b).

[67] In *United Steelworkers v. Marshall*, *supra* n. 36, 647 F.2d at 1222 n.41, the court referred approvingly to OSHA's use of a

To be sure, a second cycle will delay completion of the rulemaking, but the delay may be legally necessary or desirable from a policy point of view.[68] In any event, a decision on the second cycle will involve balancing fairness and the need for expedition.

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supplemental notice on the medical removal protection issue in the lead proceeding, and critically to the agency's failure expressly to mention in that supplemental notice the issue of an "obviously anticipated" lowering of the permissible exposure limit. The court nonetheless held that the proposal was adequate on the issue of the permissible exposure limit, since it contained sufficient suggestion of the possibility of a lower permissible exposure limit, even though "OSHA would have served the parties far better" had it listed in the proposed rule two or more alternative permissible limits. 647 F.2d at 1222.

[68] *But see Public Citizen Health Research Group v. FDA*, 724 F. Supp. 1013, 1022 (D.D.C. 1989).

PART III: INFORMAL RULEMAKING IN PRACTICE

CHAPTER 4

PUBLIC PARTICIPATION

Section 553 of the Administrative Procedure Act provides that "the agency [in informal rulemaking] shall give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments *with or without opportunity for oral presentation.*"[1] The APA thus mandates that rulemaking include an opportunity for written comment, but leaves to agencies the decision whether to allow oral presentation of data and views. Some enabling statutes specify a minimum comment period or mandate that public hearings be held; these statutes may also contain other requirements for participation by the public or other groups.[2] This chapter discusses public participation in the rulemaking process, focusing particularly on the general function of written comments in rulemaking. The role of oral hearings in rulemaking is then considered.

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[1] 5 U.S.C. § 553(c) (emphasis added).

[2] *See, e.g.*, Resource Conservation and Recovery Act (RCRA), 42 U.S.C § 6924(a), requiring EPA, within a specified time limit, to promulgate regulations for the treatment, storage or disposal of hazardous waste, "after opportunity for public hearings and after consultation with appropriate Federal and State agencies."

Public Participation

A. Opportunity For Written Comment

The previous chapter's discussion of notices of proposed rulemaking noted that the APA does not specify a minimum time for submission of written comments.[3] Little case law exists relating specifically to the length of the comment period. Reviewing courts apparently are more concerned with the overall adequacy of the opportunity to comment; the length of the comment period is only one factor to be considered.[4] The adequacy of the opportunity to comment often turns on steps the agency took, or failed to take, to apprise interested persons of important data or information in its possession.

The fact that reviewing courts have not focused specifically on the time allowed for comment does not mean that agency practice is always sufficient to permit the submission of informed comment. As noted earlier,[5] there is a misconception that the APA establishes a minimum comment period of 30 days. But even assuming interested persons receive notice the day it is published in the Federal Register, thirty days may be an inadequate period of time for people to respond to proposals that are complex or based on scientific or technical data. "Interested persons" often are large organizations, which may need time to coordinate an organizational response or to authorize expenditure of funds to do the research needed to produce informed comments.

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[3] *Supra*, Part III, Ch. 3(B).

[4] *See, e.g., Florida Power & Light Co. v. U.S.*, 846 F.2d 765, 772 (D.C. Cir. 1988), *cert. denied*, _ U.S. _, 109 S. Ct. 1952 (1989) (15-day comment period not unreasonable in circumstances); *Connecticut Light & Power Co. v. NRC*, 673 F.2d 525, 534 (D.C. Cir.), *cert. denied*, 459 U.S. 835 (1982) (30 days not unreasonable in light of industry familiarity with problem).

[5] *Supra*, Part III, Ch. 3(B).

The APA's legislative history indicates that the notice of proposed rulemaking "must be sufficient to fairly apprise interested parties of the issues involved, so that they may present responsive data or argument."[6] This language was not intended to require an agency, in informal rulemaking, to give interested persons an opportunity to attack the agency's factual basis or to develop "evidence" countering that of the agency. Rules developed through notice-and-comment procedure had to be rational; the agency had no duty to produce "substantial evidence" in support of its rule.[7] Consequently, it was not envisioned at the time the APA was enacted that interested persons must be given significant time to generate contrary factual information during the public rulemaking proceeding. Rather, the section 553 notice-and-comment opportunity was intended to give interested persons a chance to submit available information to the agency to enhance the agency's knowledge of the subject matter of the rulemaking.[8]

The traditional view of section 553 procedure as a process for educating the agency has been gradually replaced, in practice if not in theory, by the belief that informal rulemaking procedure should provide interested persons an opportunity to "challenge the factual assumptions on which [the agency] is proceeding and to show in what respect such assumptions are erroneous."[9] In other words, the public must be informed of the data and assumptions on which the agency's proposal is based.

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[6] Legislative History of the Administrative Procedure Act, S. Doc. No. 248, 79th Cong., 2d Sess. 200 (1946).

[7] *See* Gifford, *Rulemaking and Rulemaking Review: Struggling Toward a New Paradigm*, 32 Admin. L. Rev. 577, 588-89 (1980). *See also* Part IV, Ch. 2.

[8] *See* Auerbach, *Informal Rule Making: A Proposed Relationship Between Administrative Procedures and Judicial Review*, 72 Nw. L. Rev. 15, 21-23 (1977).

This change stems largely from courts that have been called upon to review, often in a preenforcement setting,[10] complex, scientifically-based agency rules. A leading case in this area is *Portland Cement Assocication v. Ruckelshaus.*[11] In adopting new source performance standards for portland cement plants under the Clean Air Act, the Environmental Protection Agency published a statement with its final rule indicating that the agency relied on test results that had not been made available for public comment. The District of Columbia Circuit held there was "a critical defect in the decision-making process in arriving at the standard . . . in the initial inability of petitioners to obtain -- in timely fashion -- the test results and procedures used . . . [in determining the final standard]."[12] The court went on to state that "[i]t is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data, or on data that, [in] critical degree, is known only to the agency."[13] Later cases involving EPA rules followed the reasoning of *Portland Cement*,[14] as have cases in other areas.[15]

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[9] H. Rep. No. 93-1606, 93rd Cong., 2d Sess. 33 (1974)(Conference Report, Magnuson-Moss Warranty--Federal Trade Commission Improvement Act).

[10] *See* Part IV, Ch. 1(E)(2), *infra*, for a discussion of preenforcement judicial review.

[11] 486 F.2d 375 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974).

[12] *Id.* at 392.

[13] *Id.* at 393.

[14] *E.g., Ethyl Corp. v. EPA*, 541 F.2d 1, 48-49 (D.C. Cir.), *cert. denied*, 426 U.S. 941 (1976).

In a 1985 case involving Medicare rules, *Lloyd Noland Hospital & Clinic v. Heckler*,[16] the Eleventh Circuit reaffirmed the principle that "[w]hen a proposed rule is based on scientific data, the agency should identify the data and methodology used to obtain it."[17] The court, citing *Portland Cement*, held that the original agency notice, which cited only a "study conducted by an HEW consultant . . .", standing alone, was legally inadequate where the specific study was not identified until the final rule.[18] However, because a copy of the study was sent to three affected hospital associations, and many individual members of the associations submitted comments on it, the court, "[b]ased on the number and relative uniformity of responses," held that there was sufficient "actual notice" to cure any defects in the original notice.[19]

The court decisions suggest that an agency that discovers new and important factual information, or new methods of analyzing the data, that are relevant to the rulemaking and does not notify interested persons of its availability and allow comment on it may be running a risk of reversal if the rule is

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[15] The court in *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977), a case involving the FDA, focused on the need for full disclosure of scientific research being relied on in order to generate meaningful public comment. *Id.* at 252.

[16] 762 F.2d 1561 (11th Cir. 1985).

[17] *Id.* at 1565.

[18] *Id.*

[19] *Id.* at 1565-66. *See also City of Stoughton v. EPA*, 858 F.2d 747 (D.C. Cir. 1988), where the court upheld an EPA rule against a challenge that EPA had not made a consultant's report available to the public, saying that the agency had adequately set forth its theory on the issue in question early in the proceeding, and commentors had an opportunity to, and in fact did, specifically address the very issues raised. *See also* discussion of existence of public comments on a particular issue as evidence of adequate notice, *supra*, Part III, Ch. 3(D).

challenged in court. These cases raise the question to what extent agencies should routinely make information in their files, or information submitted by interested persons, available to the public for comment during rulemaking.

As a matter of sound rulemaking practice, the agency should consider making all information generated during a pre-NPRM investigation available for comment by interested persons early in the rulemaking, unless it is exempt from disclosure under the Freedom of Information Act.[20] Similarly, all written comments submitted by interested persons should promptly be placed in the rulemaking file, so that persons who later submit comments can refer to them. As noted above, a second cycle of notice and comment may be desirable or necessary in certain circumstances.[21] But the opportunity for comment has to end somewhere, and the agencies may have to make hard judgments about the need to re-open the record to receive additional comment.

In summary, there are practical limits to agency information dissemination in rulemaking, but nevertheless, it is generally in the interest of both the agency and interested persons to have the agency provide information that will bring forth the most relevant and focused comments.

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[20] *See* 5 U.S.C. § 552(b)(1)-(9) (Freedom of Information Act's exemptions). Following this advice will consume time and resources, but if the rulemaking is at all controversial, FOIA requests for this material may be expected. Therefore, the question becomes one of timing, and an agency staff may ultimately benefit from not having to divert its efforts to do this work midway through a rulemaking proceeding.

[21] Recommendation No. 76-3, "Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking," 1 C.F.R. § 305.76-3, at ¶ 1(a) and (b), discussed *supra*, Part III, Ch. 3(F).

In general, where an agency has not provided opportunity for comment before issuing a rule subject to notice-and-comment requirements, post-promulgation comments will not serve as an adequate substitute.[22] Courts have voiced concerns that an agency will be less likely to change its mind after a rule is in place, and the public is less likely to participate in what appears to be a *fait accompli.* Courts have, however, sometimes taken into account an agency's response to post-promulgation comments in deciding whether to uphold a rule that should have been issued after notice and comment. Where an agency's response suggests that it has been open-minded in considering comments, "the presumption against a late comment period can be overcome and a rule upheld."[23] This is not the preferred process, however.[24]

B. Use of Hearings in Rulemaking

The APA gives agencies the discretion whether or not to hold oral hearings in informal rulemaking. However, some specific statutes require that agencies provide an opportunity for oral presentation of data or views or a public hearing,[25] and a few statutes require agencies to provide an opportunity for cross-examination in informal rulemaking.[26]

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[22] *Air Transport Ass'n v. DOT*, 900 F.2d 369 (D.C. Cir. 1990).

[23] *Levesque v. Block*, 723 F.2d 175, 188 (1st Cir. 1983). *Compare Air Transport Ass'n, supra* n. 22.

[24] *Levesque v. Block, supra* n. 23. Where notice and comment are not required, such as in cases involving interpretive rules or "good cause," the Administrative Conference recommends providing opportunity for post-promulgation comment, in order to identify shortcomings in the rule, and to assist a reviewing court in determining the reasonableness of the agency's position. Recommendation No. 76-5, "Interpretive Rules of General Applicability and Statements of General Policy," 1 C.F.R. § 305.76-5; Recommendation No. 83-2, "The 'Good Cause' Exemption From APA Rulemaking Requirements," 1 C.F.R. § 305.83-2. *See also* Part II, Ch. 1(D)(2),(3).

1. *The Administrative Procedure Act*

As noted at the beginning of this chapter, section 553 of the APA requires agencies to give the public notice and an opportunity to comment on a proposed rule "with or without opportunity for oral presentation."[27] The APA does not mandate an oral hearing in *informal* rulemaking. However, section 553(c) provides that for *formal* rulemaking, *i.e.*, "[w]hen rules are required by statute to be made *on the record after opportunity for an agency hearing*, sections 556 and 557 of this title apply . . . ."[28] Sections 556 and 557 contain requirements for trial-type hearings, including the right of interested parties to present evidence, conduct cross-examination of witnesses who introduce opposing evidence, and submit rebuttal evidence, and the rulemaking record is the exclusive basis for the decision.[29]

In the early 1970s, the Supreme Court issued two important decisions concerning the application of these APA rulemaking provisions. In *United States v. Allegheny-Ludlum Steel Corp.*,[30] the Supreme Court held that even though section

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[25] *See, e.g.*, 42 U.S.C. § 6924(a) (RCRA), *supra* n. 2; 29 U.S.C. § 655(b) (Occupational Safety and Health Act).

[26] *See* subs. (2), *infra*.

[27] 5 U.S.C. § 553(c).

[28] *Id.* (Emphasis added.)

[29] For a brief summary of procedural requirements for formal rulemaking, *see* discussion *supra*, Part II, Ch. 1(B).

[30] 406 U.S. 742 (1972).

1(14)(a) of the Interstate Commerce Act provides that rules must be adopted "after hearing," the Interstate Commerce Commission (ICC) did not violate the APA when it promulgated freight car service rules under that section without holding a "trial-type" or evidentiary hearing in accordance with the formal rulemaking provisions of the APA. The Court read section 553(c) narrowly and concluded that since the Interstate Commerce Act did not require rules to be made *on the record* after a hearing, sections 556 and 557 did not apply. Therefore, a requirement for a hearing in a statute does not, without more, trigger the APA's formal rulemaking requirements.[31]

In *United States v. Florida East Coast Railway*,[32] the Court went even further. In that case, a subsequent ICC rule was challenged on the ground that the ICC's rulemaking procedure was deficient because it did not afford affected persons any oral hearing opportunity. Appellants argued that, even if the formal rulemaking provisions of the APA were not triggered, the Interstate Commerce Act gave them a right to something like a trial-type hearing. The Supreme Court rejected the appellants' contention that they were entitled to present evidence orally, cross-examine opposing witnesses, and present oral argument to the agency decisionmaker. The Court concluded that a statutory requirement of a hearing may, in some circumstances, be satisfied by procedures that meet only the standards of section 553.[33] In other words, notice-and-comment procedure may satisfy a "hearing" requirement.[34]

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[31] *Id.* at 757.

[32] 410 U.S. 224 (1973).

Although the petitioners in *Florida East Coast Railway* did not claim they were denied constitutional due process by the ICC's procedures, the Supreme Court made clear that, in legislative rulemaking, notice-and-comment procedure ordinarily comports with due process.[35] Only when a rulemaking singles out a particular person for special consideration will an oral hearing be required.[36]

2. *Hearing Requirements in Hybrid Rulemaking Statutes*

Although the APA does not contain an oral hearing requirement for informal rulemaking, a number of laws enacted in the 1970s contain requirements that the agency hold a "public hearing" or provide interested persons "an opportunity for the oral presentation of data, views, or arguments" in rulemaking. Statutes calling for a legislative-type hearing include the Occupational Safety and Health Act (1970);[37] the

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[33] *Id.* at 240-41.

[34] Since this case involved rate-making, which traditionally has been conducted using formal procedures, some observers agree with the Court's dissenters that *Florida East Coast Railway* was a "sharp break with traditional concepts of procedural due process." 410 U.S. 224, 246 (Douglas J., dissenting). *See* 1 K. Davis, Administrative Law Treatise §§ 6:22-6:23 (2d Ed. 1978); *Cf.* Nathanson, *Probing the Mind of the Administrator: Hearing Variations and Standards of Judical Review Under the Administrative Procedure Act and Other Federal Statutes*, 75 Colum. L. Rev. 721, 769 (1975).

[35] 410 U.S.C. at 242-46.

[36] *Id.* at 245-46. *Cf. Pickus v. United States Board of Parole*, 543 F.2d 240, 244-45 (D.C. Cir. 1976).

[37] 29 U.S.C. § 655.

Consumer Product Safety Act (1972);[38] the Safe Drinking Water Act (1974);[39] the Energy Policy and Conservation Act (1975);[40] the Clean Water Act (1977);[41] the Federal Mine Safety and Health Amendment Act (1977)[42]; and the Endangered Species Act Amendments (1978).[43]

A few of these hybrid rulemaking statutes require not only a legislative-type hearing, but also an opportunity for interested persons to question or cross-examine opposing witnesses. These include the Magnuson-Moss Warranty -- Federal Trade Commission Improvement Act (1975):[44] the Securities Acts Amendments (1975);[45] and the Toxic Substances Control Act (1976).[46] Some agencies have provided by regulation for questioning of witnesses.[47]

The enactment of statutes requiring an oral hearing likely reflected the growing complexity of the issues involved in informal rulemaking, the perceived need to probe the accuracy of public comments on these issues, and the strong belief among legislators in the value of oral communication between regulators and the regulated. However, most of the statutes containing hybrid rulemaking requirements were enacted in the 1970s. The recent trend seems to be away from such additional requirements.[48]

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[38] 15 U.S.C. §§ 2056, 2058.
[39] 42 U.S.C. § 300g-1(d).
[40] 42 U.S. §§ 6295, 6306.
[41] 42 U.S.C. § 7606(d).
[42] 30 U.S.C. § 811.
[43] 16 U.S.C § 1533.
[44] 15 U.S.C. § 57a.
[45] 15 U.S.C. § 78f(e).
[46] 15 U.S.C. §§ 2605.
[47] *See, e.g.*, 29 C.F.R. § 1911.15(a)(3) (OSHA regulations) ("The oral hearing shall be legislative in type. However, fairness may require an opportunity for cross-examination on crucial issues.")

3. *The Position of the Administrative Conference on Hearings in Rulemaking*

The Administrative Conference has addressed the issue of hearings in informal rulemaking in several Recommendations. In Recommendation No. 72-5,[49] the Conference recommended that (1) Congress ordinarily should not impose mandatory procedures beyond those required by section 553;[50] (2) Congress should never require trial-type procedures for resolving questions of policy or general fact (in contrast to "specific" or "adjudicative" fact);[51] and (3) agencies should decide in the light of the needs of particular proceedings whether to employ additional procedures, including "a public-meeting type of hearing, or trial-type hearing for issues of specific fact."[52]

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[48] As discussed *supra*, Part I, the trend toward court-imposed additional rulemaking was halted by the Supreme Court decision in *Vermont Yankee* in 1978. The strong emphasis on deregulation after 1981 sharply reduced the number of regulatory statutes enacted and thus use of hybrid rulemaking. *But see* 20 U.S.C. § 2831 (requiring regional meetings and use of negotiated rulemaking by Department of Education).

[49] "Procedures for the Adoption of Rules of General Applicability," 1 C.F.R. § 305.72-5.

[50] *Id.*, ¶2.

[51] *Id.*, ¶3. The distinction has often been drawn between the type of "factual" questions that arise in rulemaking proceedings, *i.e.*, questions of "policy", "general fact", or "legislative fact", and those that arise in adjudication, referred to as questions of "adjudicative" fact. On this distinction, *see* Davis, 2 Administrative Law Treatise (2d 2d.) §§ 12.3 - 12.4 (1979).

[52] Recommendation No. 72-5, §5.

While opposing across-the-board, statutorily-mandated additions to section 553 prcoedure, the Conference has recommended that agencies, in appropriate circumstances, enlarge the opportunity for public participation in informal rulemaking by employing procedures beyond a single round of notice and comment. It recommended such mechanisms as providing for a second cycle of notice and comment, holding public conferences where allowing participants to question each other would be effective in clarifying or narrowing the disputed issues, providing a fuller statement of issues in the proposal, and allowing oral argument or other oral presentations at which the presiding official could ask questions.[53]

In a 1982 Statement, "Views of the Administrative Conference on Proposals Pending in Congress to Amend the Informal Rulemaking Provisions of the Administrative Procedure Act,"[54] the Conference recommended that "an opportunity for oral presentation of data and views should not be a mandatory requirement in rulemaking under section 553 even if the requirement is limited, . . . to 'major' rulemakings."[55] The Conference reaffirmed its earlier position that agencies should use oral hearings in appropriate circumstances, but concluded that "agencies should have discretion to decide when and to whom the presentations are made."[56] Finally, the Conference advised Congress not to enact provisions in the bills that would require cross-examination in rulemaking, even though these bills would have required cross-examination only as a "last resort" procedure.[57]

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[53] Recommendation No. 76-3, "Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking," 1 C.F.R. § 305.76-3.

[54] 1 C.F.R. § 310.7.

[55] *Id.* at ¶2.

[56] *Id.*

4. *Agency Hearing Procedures*

Agencies have adopted several procedural approaches in determining whether and when to hold legislative-type hearings in rulemakings under section 553. Where the hearing is required by statute, but only on request,[58] the agency may publish a proposal, request written comments, and wait until one or more requests are received and evaluated before directing a hearing.[59] Where the statute requires a hearing, or it is clear that the issues are such that a hearing will be needed, an agency may set the hearing date in the initial proposal in anticipation of requests for a hearing.[60] Where time is a factor, as for example when there is a judicial deadline, the agency may also wish to set a hearing in its initial proposal.[61] An agency may announce in its NPRM that a hearing is being considered and then await public reaction before making its decision on the hearing.[62] Where the statute does not require a hearing, the agency may exercise its discretion to call the hearing at any stage of the process.[63]

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[57] *Id.*, ¶3. The FTC is one of the few agencies with extensive experience using cross-examination in rulemaking. 15 U.S.C. § 57a(c)(2)(B). At Congress' request, the Administrative Conference studied the FTC's experience. *See* Recommendation No. 79-1, "Hybrid Rulemaking Procedures of the Federal Trade Commission," 1979 ACUS Recommendations & Reports 3; Recommendation No. 80-1, "Trade Regulation Rulemaking Under the Magnuson-Moss Warranty-FTC Improvement Act," 1980 ACUS Recommendations & Reports 3. After analyzing the FTC procedure, the Conference reaffirmed its view that "Congress should not ordinarily require, for agency rulemaking, procedures in addition to those specified by section 553 of the [APA], although the agencies should have the discretion to utilize them." *Id.* ¶ B.2.

[58] *See, e.g.*, OSH Act, 29 U.S.C. § 655(b)(3) ("any interested person may file with the Secretary [of Labor] written objections to the proposed rule, stating the grounds therefore and requesting a public hearing on such objections"). *See* 29 C.F.R. § 1911.11(b)(4), (c).

[59] *See, e.g.*, Occupational Safety and Health Administration, Explosive and Other Dangerous Atmospheres in Vessels and Vessel Sections, Notice of Proposed Rulemaking, 53 Fed. Reg. 48,092, 48,105 (1988) (inviting written comments on proposal and advising that interested person may file objections to the proposal and request an informal hearing).

Where a legislative-type rulemaking hearing will be conducted, the agency must determine the specific procedures that will be followed. In some cases, the enabling statute will stipulate the procedures that must be followed.[64] In others, agency rulemaking regulations may establish general procedures.[65] In any event, the agency will usually state the procedural ground rules for the hearing in its notice the hearing.[66]

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[60] *See* EPA, National Emission Standard for Hazardous Air Pollutants, Benzene Emissions from Various Sources, Proposed Rule and Notice of Public Hearing, 53 Fed. Reg. 28,496, 28,571 (1988) (setting public hearing in acccordance with § 112(b)(1)(B) and § 307(d)(5) of Clean Air Act); Occupational Safety and Health Administration, Air Contaminants, Proposed Rule, 53 Fed. Reg. 20,960, 21,262 (1988) (setting informal hearing under § 6(b)(3) of OSH Act).

[61] *See, e.g*, Occupational Safety and Health Administration, Occupational Exposure to Ethylene Oxide, Proposed Rule, 48 Fed. Reg. 17,283 (1983). The District of Columbia Circuit had ordered OSHA to issue a proposed standard within thirty days and strongly urged that a final standard be issued within a year. *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983).

[62] *See, e.g.*, Federal Highway Administration, Motor Carrier Safety Standards, Controlled Substances, Notices of Proposed Rulemaking, 53 Fed. Reg. 22,268 (1988) (90 days allowed for written comments; agency indicated that it is "also considering holding a public hearing on this proposal, and if so, will announce the time and place of the hearing in the Federal Register.")

[63] Agencies sometimes set a series of hearings, either because they wish to facilitate nationwide participation or because the issues involved are of special interest to particular parts of the country. *See, e.g.*, National Labor Relations Board, Collective Bargaining Units in the Health Care Industry, Second Notice of Proposed Rulemaking, 53 Fed. Reg. 33,900 (1988) (requesting second cycle of public comments and describing first round of public hearings held in various cities).

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[64] *E.g.*, FTC Improvements Act of 1980, 15 U.S.C. § 57a(c)(2); 15 C.F.R. § 1.14. For an application of these procedures, *see, e.g.*, Federal Trade Commission, Funeral Industry Practices Trade Regulation Rule, Notice of Proposed Rulemaking, 53 Fed. Reg. 19,864, 19,871-72 (1988) (setting public hearing and specifying procedures).

[65] *See, e.g.*, OSHA, 29 C.F.R. § 1911.15 - .17 ("Nature of hearing," "Powers of presiding officer" and "Certification of the record of a hearing.")

[66] Among the procedural issues that may need to be addressed are (1) who will preside at the hearing; (2) any requirements individuals wishing to testify at the hearing must satisfy; (3) whether cross-examination will be permitted; (4) what will be the agency's role at the hearing, including whether it will present witnesses in support of its proposal; and (5) what post-hearing procedures will be provided. *See, e.g.*, OSHA, Air Contaminants, Proposed Rule, 53 Fed. Reg. 20,960, 21,262 (1988) (setting informal hearing under § 6(b)(3) of Act); FTC, Funeral Industry Practices Trade Regulation Rule, *supra* n. 64, 53 Fed. Reg. at 19,872; EPA, National Emmission Standards for Hazardous Air Pollutants, Benzene Emissions, *supra* n. 60, 53 Fed. Reg. at 28,571 (persons desiring to appear at hearing must contact EPA; oral statements limited to 10 minutes; written statements may be filed before, during or within 30 days of hearing). For an account of OSHA practice, *see* Mintz, OSHA: History, Law, and Policy 64-67 (1984).

PART III: INFORMAL RULEMAKING IN PRACTICE

CHAPTER 5

THE RULEMAKING RECORD

The development of the concept of the rulemaking record or file has been one of the most significant changes in informal rulemaking procedure since the APA was enacted. Although debate remains about its function, a consensus has emerged that a rulemaking record or file should be created in informal rulemaking.

A. The Evolution of the "Rulemaking Record" Concept

When the APA was enacted, it was not generally thought that agencies needed to develop factual support for legislative rules.[1] Of course, agencies frequently would have developed factual support for a rule in anticipation of a court challenge, if not simply as a matter of sound agency practice.[2] In fact, the legislative history of section 553 indicates that the Act's drafters expected agencies to use their discretion to develop supporting records if the nature of the particular proceeding required it.[3]

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[1] Professor Kenneth Culp Davis describes the original understanding as follows:

> In making rules of general applicability, agencies were generally free, in absence of special statute, to develop factual materials or not to develop them, as they saw fit, unless a party subject to a rule attempted to rebut the presumption [of the existence of facts justifying the rule] on judicial review. Such freedom of agencies was understood and accepted at the time of enactment of the [APA] in 1946. Nothing in the APA changed the presumption.

1 K. Davis, Administrative Law Treatise § 6:1 at 449 (2d ed. 1978).

One reason the APA drafters were content to give agencies discretion to develop record support for legislative rules was that when the APA was enacted, the validity of rules generally was determined on judicial review of an agency enforcement action. A record for review was thus developed either in the agency proceeding or *de novo* in the reviewing court.[4]

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[2] *See* Report of the Attorney General's Committee on Administrative Procedure in Government Agencies, S. Doc. No. 8, 77th Cong., 1st. Sess. 111-14 (1941), for a description of agency investigational practices.

[3] The legislative history provides:

> The first sentence [of § 4 of the APA, now 5 U.S.C. § 553] states the minimum requirements of public rulemaking procedure short of statutory hearing. Under it agencies might in addition confer with industry advisory committees, consult organizations, hold informal "hearings," and the like. Open proceedings may be aided by the submission of reports or summaries of data by agency representatives. . .
>
> Considerations of practicality, necessity, and public interest as discussed in connection with section 4 (a) will naturally govern the agency's determination of the extent to which public proceedings may be carried. *Matters of great import, or those where the public submission of facts will be either useful to the agency or a protection to the public, should naturally be accorded more elaborate public procedures. The agency must keep a record and analyze and consider all relevant matter presented prior to the issuance of rules. The required statement of the basis and purpose of rules issued should not only relate to the data so presented but with reasonable fullness explain the actual basis and objectives of the rule.*

House Comm. on the Judiciary, Report on the Administrative Procedure Act, H.R. Rep. No. 1980, 79th Cong., 2d Sess. 259 (1946) (emphasis supplied).

Another reason for the latitude given agencies to produce factual support for rules was the presumption in favor of the existence of facts supporting a rule. This presumption was established by *Pacific States Box & Basket Co. v. White*,[5] a case where the Supreme Court applied the "rational basis" test used in review of legislation to rulemaking (a "quasi-legislative" process). The effect of this presumption was to place upon a rule challenger the burden of disproving supporting factual premises and rationales for the rule, at least as applied to it. The agency had no burden to show, in the first instance, factual support for the rule.[6]

Around 1970, reviewing courts, especially in the environmental area, began to back away from *Pacific States Box*

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[4] *See* Auerbach, *Informal Rule Making: A Proposed Relationship Between Administrative Procedures and Judicial Review*, 72 Nw. L. Rev. 15, 24-25 (1977).

[5] 296 U.S. 176 (1935).

[6] *See* Gifford, *Rulemaking and Rulemaking Review: Struggling Toward a New Paradigm*, 32 Admin. L. Rev. 577, 582-90 (1980), for a full discussion of the presumption of validity. It should be noted that the APA's provisions for formal rulemaking, required to be conducted under the procedures in §§ 556 and 557, stand in sharp contrast with those required for informal rulemaking under § 553. In formal rulemaking, the proponent of a rule has the burden of proof, and the final rule must be supported by "reliable, probative, and substantial evidence," 5 U.S.C. § 556(d). The "transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision" in such rulemaking, 5 U.S.C. § 556(e). Formal rulemaking is commonly called "on-the-record" rulemaking because of these requirements.

& *Basket's* deferential review of informal rulemaking. In *Citizens to Preserve Overton Park v. Volpe*,[7] the Supreme Court stated that, although agency action is entitled to a presumption of regularity, "that presumption is not to shield [the] action from a thorough, probing, in-depth review."[8] In rejecting the argument that the case be remanded to the agency for formal findings, the Court stated that the delay involved in the remand would be unnecessary since "there is an administrative record that allows the full, prompt review of the [S]ecretary [of Transportation]'s action." However, the Court refused to accept as the record in the proceeding the agency's "'post hoc' rationalizations" of the decision in the form of litigation affidavits. The Court therefore remanded the case to the district court for "plenary review," which was to be "based on the full administrative record that was before the secretary at the time he made his decision."[9]

While *Overton Park* itself did not involve agency rulemaking,[10] it has been a major influence on the standard of court review of agency rulemaking and of the requirement for a record as a basis for court review.[11] Cases such as *Portland*

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[7] 401 U.S. 402 (1971), discussed *supra*, Part I(B).
[8] *Id.* at 415.
[9] *Id.* at 420-21.
[10] The action in *Overton Park* would be characterized as informal adjudication, since it involved the release of federal funds to a state highway department for highway construction through a public park.
[11] *Overton Park* was cited in more than 650 federal court opinions just in the period between March 1971, when the case was decided, and December 1978. Rodgers, *A Hard Look at Vermont Yankee: Environmental Law Under Close Scrutiny*, 67 Geo. L.J. 699, 716 n. 126 (1979). *See also* DeLong, *Informal Rulemaking and the Integration of Law and Policy*, 65 Va. L. Rev. 257, 262-76 (1979).

Cement Ass'n v. Ruckelshaus[12] and *United States v. Nova Scotia Food Products*[13] further promoted the growth of "records" in informal proceedings by requiring agencies to make available for public comment important studies and other data on which they rely in determining the final rule.[14]

The rulemaking record's importance in the review process was articulated by the District of Columbia Circuit in 1977 in *Home Box Office, Inc. v. FCC*[15] as follows: "Whatever the law may have been in the past, there can now be no doubt that implicit in the decision to treat the promulgation of rules as a 'final event' in an ongoing process of administration is an assumption that an act of reasoned judgment has occurred, an assumption which further implicates the existence of a body of material -- documents, comments, transcripts, and statements in various forms declaring agency expertise or policy -- with reference to which such judgment was exercised."[16] It is "against this material," the court in *Home Box Office* said, that it is "the obligation of this court to test the actions of the

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[12] 486 F.2d 375 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974).

[13] 568 F.2d 240 (2d Cir. 1977).

[14] *Nova Scotia* involved a challenge to an FDA rule in the context of an enforcement proceeding. The rule was challenged on the grounds that FDA had failed to follow proper notice-and-comment procedures in promulgating the rule. The court upheld the challenge, in part on the basis that the agency had failed to make or certify a "contemporaneous record" which included certain scientific studies relied on in promulgating the rule at the time of the original rulemaking agency proceeding. 568 F.2d at 249.

[15] 567 F.2d 9 (D.C. Cir.), *cert. denied*, 434 U.S. 829 (1977).

[16] *Id.* at 54 (citations omitted).

[agency] for arbitrariness or inconsistency with delegated authority."[17]

Congress, in enacting hybrid rulemaking statutes, has specifically required agencies to have "record" support for final rules, and some of these statutes explicitly require the agency to maintain a rulemaking record or file for judicial review.[18] The Clean Air Act has particularly detailed record requirements.[19]

The comprehensive regulatory reform bills considered by Congress in 1982 would have required agencies to maintain a rulemaking file and to include certain material in the file.[20]

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[17] *Id.*, citing *Overton Park*. As discussed in Part III, Ch. 6, *infra*, *Home Box Office* involved issues of ex parte communications. While the case's holding on that issue has been narrowed, such narrowing would not appear to affect the principle cited here.

[18] *See, e.g.*, Magnuson-Moss Warranty -- FTC Improvements Act, 15 U.S.C. § 57a(e)(1)(B); Toxic Substances Control Act, 15 U.S.C. § 2618 (1976); Consumer Product Safety Act, 15 U.S.C. § 2060(a); Clean Air Act, 42 U.S.C. § 7607(d)(7)(A); OSH Act, 29 U.S.C. § 655(f).

[19] 42 U.S.C. § 7607(d)(2)-(4). It requires EPA to establish a "docket" no later than the date on which the NPRM is published. The Act expressly requires EPA promptly to place all written comments and documentary information received in the docket. EPA must also place in the docket "as soon as possible after their availability" all documents which became available after the proposed rule has been published and which "the Administrator [of EPA] determines are of central relevance to the rulemaking . . . ." 42 U.S.C. § 7607(b)(4)(B)(i). The statute also requires that EPA place in the record drafts of proposed and final rules and accompanying documents submitted to OMB for review, and written comments by other agencies, as well as the EPA Administrator's written responses. 42 U.S.C. § 7607(d)(4)(B)(ii). Requirements for disclosure of drafts and other documents involved in the OMB review process is discussed *infra*, Part III, Ch. 6(C).

[20] *See* S. 1080, Regulatory Reform Act, § 3 (passed by the Senate on Mar. 24, 1982); H.R. 746, Regulatory Procedure Act § 201 (reported by the House Judiciary Committee on Feb. 25, 1982).

The Administrative Conference reacted to these proposals by supporting a rulemaking file requirement in the APA, although the Conference's recommended language differed somewhat from the bill provisions.[21]

The development of the concept of a "rulemaking record" for informal rulemaking is also reflected in Executive Order No. 12,291 on Federal Regulation, which states that before approving any final major rule, each agency shall:

> [M]ake a determination that the factual conclusions upon which the rule is based have substantial support in the agency record, viewed as a whole, with full attention to public comments in general and the comments of persons directly affected by the rule in particular.[22]

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[21] The Conference recommended that:

> Congress amend the APA to provide that, in rulemaking under section 553, an agency shall maintain a public rulemaking file beginning no later than the date on which the notice of proposed rulemaking is published. At a minimum, the agency should be required to place in the public rulemaking file, promptly upon receipt or production, the following materials: (1) all notices pertaining to the rulemaking, (2) copies, or where impractical a reference to or index of, all factual material upon which the agency substantially relied in formulating the proposed or final rule, unless the material is by law exempt from disclosure, (3) all written comments submitted by interested persons during the rulemaking, and (4) any other material required by statute or agency rule to be made public in connection with the rulemaking.

Views of the Administrative Conference on Proposals Pending in Congress to Amend the Informal Rulemaking Provisions of the APA, ¶ 4, 1 C.F.R. § 310.7 (1989).

[22] Exec. Order No. 12,291, § 4.

B. The Importance of the Rulemaking Record in Informal Rulemaking

Deciding what to include in the rulemaking record, and when, requires an understanding of the functions the record serves. A rulemaking record: (1) aids public participation in the rulemaking; (2) provides the basis for the agency's decision whether to adopt a rule and, if so, what provisions the rule should include; and (3) assists judicial review of the final rulemaking decision.

1. The Rulemaking Record as an Aid to Public Participation

The existence of a public rulemaking record is a critical factor in making public participation in the rulemaking meaningful. Public comments are much more likely to be focused and useful if the commenters have access to the comments of others. More ample comments benefit the agency, the public and ultimately the reviewing courts. Issues not otherwise raised by the agency's proposal may arise in the comments. There is, as noted earlier,[23] a difference of views among courts as to whether issues raised in the comments but not in the NPRM provide adequate notice to other members of the public. In any event, the exchange of views and new information in the comments may, in the agency's discretion, serve as a basis for additional rulemaking proceedings by the agency on new issues. Finally, it is noted that several hybrid rulemaking statutes require agencies to receive rebuttal comments.[24] Other agencies, although not required to do so, voluntarily give interested persons the opportunity to submit "reply comments" in rulemaking.[25] This exchange of comments becomes part of the rulemaking record.

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[23] *See* discussion *supra*, Part III, Ch. 3(D).

2. The Rulemaking Record as the Basis for the Agency's Rulemaking Decisions

A second and related function of the rulemaking record is to provide the agency decisionmaker with enough information to decide whether a final rule is warranted, and if so, what provisions it should contain. Structuring the record or file to serve both the needs of interested persons and the agency decisionmaker may be difficult in complex rulemaking proceedings. In order to avoid delay in a rulemaking, the agency staff should index and organize the record in a way that will enable both agency staff and interested parties to use the rulemaking record during the rulemaking.

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[24] *See, e.g.*, Clean Air Act, 42 U.S.C. § 7607(d)(5) (requiring EPA to keep the rulemaking record open for an additional 30 days after completion of the proceeding to allow submission of rebuttal comments). *See also* Toxic Substances Control Act, 15 U.S.C. § 2605 (c)(3)(A).

[25] FCC Rules of Practice, 47 C.F.R. § 1.415(c). Agencies often extend comment periods (after public notice in the Federal Register), raising new issues or announcing the availability of new data. Information in the agency files pertinent to the rulemaking would normally also be available to members of the public under the Freedom of Information Act, 5 U.S.C. § 552; however, there is no assurance that interested persons could obtain the information before the end of the rulemaking comment period.

3. *The Rulemaking Record as the Basis for Judicial Review*

Agencies must anticipate that courts will conduct "thorough, probing, in-depth review" of informal rulemaking, and that they will require the agency to produce an administrative record to support its final rule. The power to require submission of a record for judicial review purposes is inherent in the review function. If a reviewing court is not given the reasoning and factual justification needed to support the rationality of the rule, the court has no choice, absent a statutory provision for *de novo* review, but to remand the matter to the agency for further proceedings.

Judges have been somewhat perplexed and unhappy about some of the rulemaking records they have been called upon to review. One court described the record before it as "a sump in which the parties have deposited a sundry mass of materials that have neither passed through the filter of rules of evidence nor undergone the refining fire of adversarial presentation."[26] And at the close of a 100-plus page rulemaking review decision, a weary District of Columbia Circuit panel concluded: "We reach our decision after interminable record search (and considerable soul searching). We have read the record with as hard a look as mortal judges can probably give its thousands of pages."[27] The author of that decision, Judge Wald, stated in another forum that:

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[26] *Natural Resources Defense Council v. SEC*, 606 F.2d 1031, 1052 (D.C. Cir. 1979).

[27] *Sierra Club v. Costle*, 657 F.2d 298, 410 (D.C. Cir. 1981) (footnote omitted). *See also Ethyl Corp. v. EPA*, 541 F.2d 1, 49 n. 102 (D.C. Cir.), *cert. denied*, 426 U.S. 941 (1976).

> At times it is hard not to feel that no one seriously expects the judge to look at, let alone understand, the record. Weighing the substantiality of the evidence is perceived more as a quantitative than a qualitative exercise. Since a record search in a lengthy agency proceeding -- time constraints aside -- too often resembles a safari through uncharted lands without benefit of a guide, it is not recommended for amateurs.[28]

Several factors account for the difficulties the courts confront in examining rulemaking records. Rulemaking is essentially a legislative process, encompassing value and policy judgments as well as factual material. Even the "facts" on which the agency relies are accumulated expertise and experience of the agency and others, which are difficult if not impossible to package in the record of the proceeding. Thus, it is the nature of the proceeding itself that determines the kind of record that will reach the court. As the District of Columbia Circuit said in one of its early hybrid rulemaking decisions, "the record resembles nothing so much as that of a typical legislative committee hearing."[29]

A major issue regarding judicial review of rulemaking is whether the record on review should consist only of materials that were before the agency when it made its final decision or whether the agency may augment the record with additional facts or arguments before the reviewing court.

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[28] Wald, *Judicial Review of Complex Administrative Agency Decisions*, Annals Am. Acad. Pol. & Soc. Sci. 72 (1982).

[29] *Industrial Union Dep't v. Hodgson*, 499 F.2d 467, 471 n. 9 (D.C. Cir. 1974). The court there described the "testimonial pattern" in the record as follows: witnesses generally read "long statements" followed by "cross-examination," the questions asked "tended to be few, sporadic, and perfunctory . . . ." The case involved OSHA's rulemaking leading to the issuance of a standard regulating asbestos.

The Administrative Conference, in a 1974 Recommendation that addressed issues raised by preenforcement judicial review of informal rulemaking, recommended that certain basic rulemaking documents be included in the record before the court.[30] However, by suggesting that the agency include in the record "factual information . . . that is proferred by the agency as pertinent to the rule," the Recommendation clearly did not intend to limit review to materials that were before the agency when it made its final rulemaking decision. The Conference also did not assume that the court was "invariably confined" to the materials the agency placed in the record.[31]

Some commentators criticize Recommendation No. 74-4 for not confining judicial review to the rulemaking record or file that was before the agency when it made its final rulemaking decision. They argue that confining review to an "exclusive" rulemaking record would have a salutary disciplining effect on agencies and would aid courts in performing their review function.[32]

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[30] Recommendation No. 74-4, "Preenforcement Judicial Review Rules of General Applicability," 1 C.F.R. § 305.74-4. These included the notice, comments, transcripts of testimony, "factual information not included in the foregoing that was considered by the authority responsible for promulgation of the rule or that is proferred by the agency as pertinent to the rule," advisory committee reports, the statement of basis and purpose, and any documents referred to therein.

[31] *Id.* at ¶1.

[32] *See* Pedersen, *Formal Records and Informal Rulemaking*, 85 Yale L.J. 38, 73 (1975); 1 K. Davis, Administrative Law Treatise § 6:5 (1982 Supp.) (expressing preference for confining review to the record that was before the agency when it made

Congress has taken both approaches in enacting statutes containing definitions of the "rulemaking record" for judicial review purposes. In the Consumer Product Safety Act and the Federal Trade Commission Improvements Act, Congress adopted the "open-ended" definitional approach recommended by the Conference.[33] In other instances, Congress has specified that the record for review shall include only information that was before the agency when it made its final decision.[34]

Regardless of whether or not a statute requires that judicial review be limited to the administrative record that was before the agency when it made its decision, the rulemaking staff should anticipate court rejection of "post-hoc rationalizations" for rules,[35] and close judicial scrutiny of

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its decision). *But see Rybachek v. EPA*, 904 F. 2d 1276 (9th Cir. 1990) (court approved EPA's addition of 6000 pages into the record following the close of comments, saying that the agency could use what it needed to support its rule).

[33] The Federal Trade Commission Improvements Act, 15 U.S.C. § 15a(e)(1)(B), defines the "rulemaking record" as including the rule, the statement of basis and purpose, the transcript of hearing, written submissions, and "any other information which the Commission considers relevant to such rule." *See also* Consumer Product Safety Act, 15 U.S.C. § 2060(a).

[34] Under the Clean Air Act, 42 U.S.C. § 7607(d)(7)(A), the record for judicial review consists "exclusively" of "written comments and documentary information" on the proposed rule received during the comment period, transcript of the public hearing, all documents that "become available" after the proposed rule has been published which EPA "determines are of central relevance to the rulemaking," and the statement accompanying the promulgated rule. 42 U.S. §§ 7607(d)(4)(B)(i), 7607(d)(6)(A),(B). *See also* Toxic Substances Control Act, 15 U.S.C. § 2618.

[35] Post-hoc rationalizations are those marshalled by attorneys in a court review proceeding to justify agency actions that were not accompanied by adequate explanation of the reason for the action. *See, e.g., American Textile Inst. v. Donovan*, 452 U.S. 490, 539 (1981).

reliance on data obtained after the public stage of rulemaking. Accordingly, the agency would be well-advised, except in unusual circumstances, to include in the public file all materials on which it relies in making final rulemaking decisions, and to provide an opportunity for public comment in appropriate circumstances.

The burden on judges reviewing rulemaking has increased along with the increase in the volume, importance, and complexity of rulemaking. The agency rulemaking staff cannot do much to relieve this burden in many instances. However, it can take measures to facilitate judicial review of rulemaking records and avoid complaints like the following by former Judge J. Skelly Wright of the District of Columbia Circuit:

> Today's informal rulemaking proceedings do not provide a proper record . . . . The result is that courts spend an inordinate amount of time in review of informal rulemaking cases attempting to find documents that presumably are in the record but which are somehow unavailable. Often there is not even a list of the documents that make up the record. Perhaps the most distressing aspect of such reviews is that documents seem to surface one at a time, first from one party, then from another. And one understandably gets the uneasy feeling that the whole record is not really before the court.[36]

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[36] Wright, *New Judicial Requisites for Informal Rulemaking: Implications for the Environmental Impact Statement Process*, 29 Admin. L. Rev. 59, 61-62 (1977). Judge Wald of the District of Columbia Circuit also criticizes agency failure to make records accessible to reviewing courts as follows:

Despite the "formalization" of records in informal rulemaking, courts continue to recognize the "informality" of these proceedings.[37] In *Association of Data Processing Service Organizations v. Board of Governors*,[38] the District of Columbia Circuit, after concluding that the differences between the "arbitrary and capricious" and "substantial evidence" tests were "largely semantic,"[39] made it clear that there remained one

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> [I]t is only in recent years that many agencies have indexed the thousands of pages that compose a rulemaking "record." Even now, the agency seldom, if ever, organizes the mass of information in a way that allows reviewing judges quick access to supporting material for particular propositions. Yet the physical impossibility of a single judge -- and law clerk -- reading every page of a 10,000 page rulemaking record five years in the making puts a high priority on the organization and detailed indexing of that record.
>
> To be of greatest assistance, the record should be organized or indexed in terms of the major attacks upon the rule, preferably with summaries of the evidence or documents contained therein. But this is certainly not the usual practice.

Wald, *supra* n. 28, at 80.

[37] This principle has been recognized by the courts of appeals, particularly the District of Columbia Circuit, in deciding rulemaking issues such as ex parte communications, *Home Box Office, Inc. v. FCC*, 567 F.2d 9 (D.C. Cir.), *cert. denied*, 434 U.S. 829 (1977), *see* discussion *infra*, Part III, Ch. 6; decisionmaker bias, *Association of Nat'l Advertisers v. FTC*, 627 F.2d 1151 (D.C. Cir. 1979), *cert. denied*, 447 U.S. 921 (1980), *see* discussion *infra*, Part III, Ch. 7; and separation of functions, *United Steelworkers of America v. Marshall*, 647 F.2d 1189 (D.C. Cir. 1980), *cert. denied*, 453 U.S. 913.

[38] 745 F.2d 677 (D.C. Cir. 1984).

[39] *Id.* at 684. The *Association of Data Processing Services* decision and the standards for judicial review are discussed *infra*, Part IV, Ch. 2.

important difference between the two types of reviews. Where a statute requires that "substantial evidence" support agency decisions,[40] substantial evidence must "be found *within the record of closed-record proceedings* to which it exclusively applies."[41] With respect to the "arbitrary and capricious" standard applicable to informal rulemaking, however, the court stated that the "'administrative record' might well include crucial material that was neither shown to nor known by the private parties in the proceeding."[42] While conceding that, in informal rulemaking, "at least the most critical factual material that is used to support the agency's position on review must have been made public in the proceeding and exposed to refutation,"[43] the court concluded that the requirement does not extend to all data.[44]

The uncertainty concerning the required contents of the record before the court in informal rulemaking is related to the treatment of off-the-record communications[45] and the requirements for public comment in informal rulemaking.[46] A court decision reflecting these complex relationships is *Community Nutrition Institute v. Block*,[47] in which the District of Columbia Circuit rejected a procedural challenge to a Department of Agriculture regulation based on the agency's reliance on two scientific studies completed by agency staff after the close of the rulemaking record, and on which no opportunity for public comment had been provided. The court noted that these studies did not provide "entirely new information," but only expanded on and confirmed studies mentioned in the NPRM.[48] "Rulemaking proceedings would never end if an agency's response to comments must always be made the subject of additional comment," the court said, concluding that an agency's response to public comment may take the form of a new scientific study without requiring public comment, "unless prejudice is shown."[49] On the other hand, in *National Coalition Against the Misuse of Pesticides v. Thomas*,[50] the District of Columbia Circuit concluded that EPA should have included in the public file a memorandum explaining the agency's position on a central issue in the proceeding since it "clearly supplied information critical to informed comment on EPA's proposal to reestablish the 30 [parts per billion] tolerance, and, for that matter, to review by the court."[51] The court held, however, that the omission from the public record was harmless as to petitioners since they obtained the memorandum in question in time to comment on it.[52]

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[40] Under the applicable statute, the "substantial evidence" test applied to all actions of the Board of Governors of the Federal Reserve System. *Id.* at 685. The issue in the case was the meaning of that standard of review in the context of that statute.

[41] *Id.* at 684 (emphasis in original). Then-Judge Scalia noted that although the substantial evidence test under the APA has traditionally applied to adjudicatory proceedings, a number of recent statutes have attached substantial evidence review to informal rulemaking. *Id.* at 685.

[42] *Id.* at 684.

[43] *Id.*

[44] *Id.*, *citing* ACUS Recommendation 74-4, "Preenforcement Judicial Review of Rules of General Applicability," 1 C.F.R. § 305.74-4, discussed *supra*.

[45] Discussed *infra*, Part III, Ch. 6.

[46] Discussed *supra*, Part III, Ch. 4.

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[47] 749 F.2d 50 (D.C. Cir. 1984).

[48] *Id.* at 58. The court distinguished *Portland Cement* where, the court said, the agency relied on entirely new information that was "critical" to the determination. *See* Part III, Ch. 4, *supra*, for discussion of agency reliance in rulemaking on information known only to the agency.

[49] 749 F.2d at 58.

[50] 809 F.2d 875 (D.C. Cir. 1987). In this case, petitioners challenged EPA's having reinstated a 30 part per billion tolerance level for ethylene dibromide in imported mangos. The court held the action arbitrary and capricious.

[51] *Id.* at 884 n. 10.

A difficult issue arises respecting the record where the court is reviewing an agency action that did not involve a "proceeding" in the usual sense of the term. This issue may arise, for example, where the agency issues a rule that it believes is exempt from notice-and-comment requirements, perhaps because it is an interpretive rule or falls within the "good cause" exception. Since neither a proposal nor public comments would ordinarily exist in such a situation, the agency in the ordinary course of affairs may not have established a rulemaking file. A similar circumstance may arise where a party challenges an agency's refusal to commence rulemaking after a petition for rulemaking has been filed, or even without having filed a petition.[53] In those circumstances, there also may be no "file" or "record" to present to the court.

In such cases, the agency may establish a file after the fact and present it to the court as a basis for review. This practice obviously is problematic, since the agency's judgment on which documents should be included is likely to be self-serving and challenged by opposing parties. This may lead to controversy over what is the record.[54]

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[52] *Id.* The issue of what should be in the record is also complicated by contact between OMB and agencies. *See* Part III, Ch. 6, *infra*.

[53] Court review of agency inaction is discussed *infra*, Part IV, Ch. 3.

[54] This occurred, for example, in connection with court review of an OSHA emergency temporary standard. *See*

The Administrative Conference addressed this issue indirectly in its 1986 Recommendation, "Petitions for Rulemaking."[55] In recommending certain "basic procedures" for the consideration and disposition of petitions for rulemaking, the Conference suggested the "maintenance of a publicly available petition file." It recommended that an agency maintain a file of all pertinent documents that it considers whenever it undertakes a rulemaking action, including decisions not to commence rulemaking, and regardless of whether the rulemaking action is taken after notice and comment. Whether the file will be entirely public or some documents will be maintained as confidential is a separate issue.[56] However, the critical point is that the agency, in the event of a court challenge, would be in a position to offer this "record" to the court as an historical rather than a "manufactured" record.

Asbestos Information Association/North America v. OSHA, 727 F.2d 415 (5th Cir. 1984) (staying OSHA's asbestos emergency standard). There, *id.* at 420 n.12, the court considered unfavorable peer reviews even though the agency included in the record only favorable peer reviews on which it relied in issuing the emergency standard. To do otherwise, the court said, "would convert the reviewing process into an artificial game," citing *Amoco Oil Co. v. EPA*, 501 F.2d 722, 729 n.10 (D.C. Cir. 1974) (post-record events that confirm agency predictions permitted in record).

[55] 1 C.F.R. § 305.86-6.

[56] Certain internal documents, part of the deliberative process, may well be exempt from public disclosure. *See Wolfe v. Dept. of HHS*, 839 F.2d 768 (D.C. Cir. 1988) (*en banc*).

PART III: INFORMAL RULEMAKING IN PRACTICE

CHAPTER 6

"OFF-THE-RECORD" OR "EX PARTE" COMMUNICATIONS IN RULEMAKING

The emergence of the rulemaking record concept led to criticism of "off-the-record" or "ex parte" communications between agency decisionmakers and other persons during informal rulemaking. While most of the uncertainty about the law in this area has been removed by court decisions, the treatment of such communications in informal rulemaking raises complex issues and conflicting considerations that the agency rulemaker should be aware of during rulemaking.

A. Summary of the Law

The Administrative Procedure Act places no restrictions on ex parte communications made in informal rulemaking.[1] Indeed, the notions of "parties" and "off-the-record" contacts do not really apply in informal rulemaking under section 553, because participation in informal rulemaking is not limited to named parties, and the agency decision need not be based exclusively on the record produced during the rulemaking. However, the term "ex parte communications" is used throughout this chapter simply to mean off-the-record, private communications between agency decisionmakers and other persons concerning the substance of the agency's proposed rule.

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[1] The APA does prohibit ex parte contacts between outsiders and the decisionmaker in formal rulemaking and adjudication, 5 U.S.C. § 577(d)(1). *See also* 5 U.S.C. § 551(14) (APA's definition of "ex parte communication").

Early cases, such as *Sangamon Valley Television Corp. v. U.S.*, held that ex parte communications in informal rulemaking were improper where conflicting private claims to a valuable privilege were involved.[2] In 1977, the District of Columbia Circuit, in *Home Box Office, Inc. v. FCC*,[3] issued an opinion with language suggesting a much broader prohibition on ex parte communications in informal rulemakings:

> Once a notice of proposed rulemaking has been issued . . ., any agency official or employee who is or may reasonably be expected to be involved in the decisional process of the rulemaking proceeding, should refus[e] to discuss matters relating to the disposition of a [rulemaking proceeding] with any interested private party, or an attorney or agent for any such party, prior to the [agency's] decision.[4]

The court proceeded to set aside the FCC's revision of its rules, based on the existence of heavy ex parte lobbying of individual commissioners during the deliberative stage of the rulemaking proceeding.

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[2] 269 F.2d 221 (D.C. Cir. 1959).

[3] 567 F.2d 9 (D.C. Cir.), *cert. denied*, 434 U.S. 829 (1977).

[4] *Id.* at 57 (court's brackets and citations omitted). Judge Wright stated that "agency secrecy stands between us and fulfillment of our obligation" to "test the actions of the Commission for arbitrariness and inconsistency with delegated law." *Id.* at 54. "Equally important," he said, was the "inconsistency of secrecy with fundamental notions of fairness implicit in due process and with the idea of reasoned decisionmaking on the merits which undergirds all our adminstrative law." *Id.* at 54. This case has been the subject of extensive scholarly comment. *See, e.g.*, Gellhorn & Robinson, *Rulemaking "Due Process": An Inconclusive Dialogue*, 48 U. Chi. L. Rev. 201 (1981).

The *Home Box Office* decision's apparent broad prohibition sparked a debate within the District of Columbia Circuit, and the decision was soon limited significantly.[5] The debate was effectively ended by two later decisions that rejected its sweeping generalizations. In *United Steelworkers of America v. Marshall*,[6] the court, in an opinion written by Judge J. Skelly Wright, author of the *Home Box Office* opinion, rejected claims that an OSHA rule was procedurally defective because the agency decisionmaker engaged in ex parte communications with the rulemaking staff.[7] The court's opinion in *Steelworkers* was predicated primarily on the view that neither constitutional concerns,[8] nor the principle on which cases like *Home Box Office* were based, applied to the staff contacts that were challenged in the case.[9] The court went out of its way to distinguish the OSHA hybrid rulemaking from proceedings, such as those involved in *Sangamon* and *Home Box Office*, which resolve "conflicting private claims to a valuable privilege," and from "quasi adjudicatory" proceedings in which the "potential for bias [was] as great as that in a case of competing claims."[10]

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[5] Less than four months after *Home Box Office* was decided, a different panel of the District of Columbia Circuit rejected the reasoning of the *Home Box Office* majority. In *Action for Children's Television v. FCC*, 564 F.2d 458 (D.C. Cir. 1977), the court, agreeing with the concurrence in *Home Box Office* that the ex parte communications ban in *Home Box Office* was justified only because the rulemaking involved competing private claims to a valuable interest, ruled that in any event, *Home Box Office* should not be applied retroactively. *Id.* at 474. *See also Hercules, Inc. v. EPA*, 598 F.2d 91 (D.C. Cir. 1978) (refusing to invalidate EPA rule because of ex parte communications between agency presiding officer and rulemaking staff).

[6] 647 F.2d 1189 (D.C. Cir. 1980), *cert. denied*, 453 U.S. 913 (1981) (upholding in most respects OSHA's lead standard).

[7] For a discussion of contacts between decisionmakers and rulemaking staff, see subs. (E), *infra*.

[8] The court restated the principle that, as a general rule, due process imposes no constraints on informal rulemaking beyond those imposed by statute. *Id.*, 647 F.2d at 1215, n. 28.

[9] *Id.* at 1215-16.

Any doubts about the District of Columbia Circuit's refusal generally to apply the *Home Box Office* rationale to informal rulemaking were removed by *Sierra Club v. Costle*.[11] *Sierra Club* involved an EPA rulemaking under the Clean Air Act, and, on review, an environmental group alleged that the final air pollution standard was the product of an "ex parte blitz" that began after the close of the comment period.[12] The challenged communications were of various sorts: late comments entered in the record, and meetings between the agency and private persons, executive branch officials, and elected officials.[13] With respect to the oral communications with outsiders, the court stated:

> Oral face-to-face discussions are not prohibited anywhere, anytime, in the Act. The absence of such prohibition may have arisen from the nature of the informal rulemaking procedures Congress had in mind. Where agency action resembles judicial action, where it involves formal rulemaking, adjudication, or quasi-adjudication among "conflicting private claims to

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[10] *Id.* As an example of a quasi-adjudicatory proceeding, the court of appeals cited *United States Lines v. FMC*, 584 F.2d 519, 536-43 (D.C. Cir. 1978), where a hearing is statutorily required; in the OSHA context, a hearing is required only if requested. 647 F.2d at 1214.

[11] 657 F.2d 298 (D.C. Cir. 1981).

[12] *Id.* at 386.

[13] *Id.* at 387-91.

> a valuable privilege," the insulation of the decisionmaker from ex parte contacts is justified by basic notions of due process to the parties involved. But where agency action involves informal rulemaking of a policymaking sort, the concept of ex parte contacts is of more questionable utility.
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> Under our system of government, the very legitimacy of general policymaking performed by unelected administrators depends in no small part upon the openness, accessibility, and amenability of these officials to the needs and ideas of the public from whom their ultimate authority derives, and upon whom their commands must fall. As judges we are insulated from these pressures because of the nature of the judicial process in which we participate; but we must refrain from the easy temptation to look askance to all face-to-face lobbying efforts, regardless of the forum in which they occur, merely because we see them as inappropriate in the judicial context. Furthermore, the importance to effective regulation of continuing contact with a regulated industry, other affected groups, and the public cannot be underestimated. Informal contacts may enable the agency to win needed support for its program, reduce future enforcement requirements by helping those regulated to anticipate and shape their plans for the future, and spur the provision of information which the agency needs.[14]

Thus, *Home Box Office* did not establish a ban on off-the-record communications in rulemaking.

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[14] *Id.* at 400-01 (citations omitted). *Sierra Club* also involved the question whether, under the Clean Air Act, EPA was required to put into the rulemaking docket memoranda on its post-comment meetings with the President and members of Congress on issues involved in the rulemaking. *See* discussion *infra*, subs. (C), (D).

B. Agency Practices for Handling "Off-the-Record" Communications

1. *Policy Considerations*

The concerns expressed by Judge Wright in *Home Box Office*, and in the literature that followed in its wake, do raise issues that agencies should, and have, considered. One major concern of critics of ex parte communications in informal rulemaking is that decisionmakers may be influenced by communications made privately, which runs counter to the need for accountable government.[15] Another concern is that interested persons may be unable to reply effectively to information, proposals or arguments presented off the record. It also has been suggested that participants may have little incentive to submit thoughtful comments or carefully prepared supporting data if they believe that other interests have privileged access to decisionmakers. Assuring interested persons a chance to comment and respond to others' comments may reduce the influence of "insiders," yield new sources of information for the agency to consider in drafting the rule, and improve acceptance of the final rule.[16] There is also concern that ex parte communications may increase the likelihood that crucial information influencing the agency decision will not be available to the reviewing court.[17]

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[15] *E.g.*, Note, *Judicial Control of Ex Parte Contracts*, 27 DePaul L. Rev. 489 (1977).

[16] *See* Comment, *The Need for an Additional Notice and Comment Period When Final Rules Differ Substantially From Interim Rules*, 1981 Duke L.J. 377.

[17] *Home Box Office, Inc. v. FCC*, *supra* n. 3, 567 F.2d at 54. *Cf. Sierra Club v. Costle*, *supra* n. 11, 657 F.2d at 408 ("we do not believe that Congress intended that the courts convert informal rulemaking into a rarefied technocratic process,

Agencies should consider these issues in determining their policy on ex parte communications. While courts under existing case law are not likely, except in egregious situations, to set aside rules because ex parte contacts took place, agencies must still be sensitive to the concerns raised, and to the understandable unfavorable public reaction when the agency receives information in private discussions with persons outside the agency. On the other hand, nonpublic candid contacts between the agency and interested parties can be useful in working out tentative and compromise positions.[18]

2. *The Administrative Conference's Recommendation*

Shortly after *Home Box Office* was decided, the Administrative Conference reviewed the problem and concluded that a general prohibition in informal rulemaking of private contacts, or a requirement that every such communication be summarized and exposed on the public record, was undesirable. In Recommendation No. 77-3,[19] the Conference counseled that a general prohibition "would deprive agencies of the flexibility needed to fashion rulemaking procedures

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unaffected by political considerations or the presence of Presidential power.")

[18] *See, e.g.*, Nathanson, *Report to the Select Committee on Ex Parte Communictions in Informal Rulemaking Proceedings*, 30 Admin. L. Rev. 377 (1978); Carberry, *Ex Parte Communications in Off-the-Record Administrative Proceedings: A Proposed Limitation on Judicial Innovation*, 1980 Duke L. J. 65. *See also Sierra Club v. Costle*, *supra*, nn. 11-14. A similar approach to informal rulemaking was expressed by the District of Columbia Circuit in *Association of National Advertisers v. FTC*, 627 F.2d 1151, (D.C. Cir. 1979), *cert. denied*, 447 U.S. 921 (1980), a case involving allegations of prejudgment by an agency decisionmaker of one the major issues in a hybrid rulemaking proceeding.

[19] "Ex Parte Communications in Informal Rulemaking Proceedings," 1 C.F.R. 305.77-3, Preamble.

appropriate to the issues involved, and would introduce a degree of formality that would, at least in most instances, result in procedures that are unduly complicated, slow and expensive, and, at the same time, perhaps not conducive to developing all relevant information."[20] Recognizing the valid concerns of critics of ex parte contacts, however, the Conference called on agencies to (1) promptly place in a public file all written comments addressed to the merits of a proposed rule received after issuance of a notice of proposed rulemaking; and (2) experiment with procedures, including use of summaries and public meetings, to disclose oral communications that contain significant information or argument respecting the merits of a proposed rule.[21]

3. *Agency Practice*

Agencies take various approaches in handling ex parte communications, and the independent regulatory agencies appear to have the most restrictive policies regarding such contacts in rulemaking. The Federal Trade Commission is required by the 1980 amendments to the FTC Act to place a verbatim record or summary of ex parte contacts in the rulemaking record.[22] The Consumer Product Safety

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[20] *Id.*

[21] *Id.*, at ¶¶ 1 and 2. The Conference's Recommendation recognized that Congress or the courts might conclude that greater restrictions are appropriate in limited categories of agency proceedings in the interests of fairness or adequate judicial review. *Id.* at ¶ 5. The Conference's approach was cited with approval in *Sierra Club v. Costle, supra* n. 11, 657 F.2d at 403 n.513.

[22] 15 U.S.C. § 57a(j) (requiring FTC to publish rule (1) authorizing the FTC or its commissioners to meet with "any outside party concerning any rulemaking proceeding" and (2) requiring that notice of the meeting be included in any FTC

Commission has stringent requirements for openness of agency meetings and disclosure of communications with interested persons. Notice must be given of virtually all meetings between agency employees and outside persons; the public may attend any meeting, and summaries are kept of all meetings and telephone conversations between agency employees and interested persons.[23] The independent regulatory agencies' policies may reflect experience with the open-meeting requirements of the Government in the Sunshine Act,[24] as well as reaction to the District of Columbia Circuit's *Home Box Office* decision, which involved the Federal Communications Commission.

Executive agencies having formal policies governing ex parte communications include the Department of Transportation,[25] the EPA,[26] and the Federal Emergency

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weekly calendar and that a verbatim record or a summary of the meeting or "any communication relating to any such meeting" be kept, made available to the public and included in the record). *See* 16 C.F.R. § 1.13(c)(6) (prohibiting any presiding officer from consulting with any person or party respecting "a fact in issue" without notice and opportunity for all parties to participate); *see also* 16 C.F.R. § 1.18 (imposing requirements for including in the rulemaking record ex parte oral and written communications).

[23] *See* 16 C.F.R. Part 1012.

[24] 5 U.S.C. § 552b, requiring that certain federal agencies headed by a collegial body, a majority of whose members are appointed by the President with the advice and consent of the Senate, shall be open to public observation.

[25] DOT Order No. 2100.2 (Oct. 5, 1970). Ex parte communications are discouraged after the end of the comment period. After the NPRM is published, all communications must be reduced to writing and promptly placed in the public docket. Summaries should include list of participants; summary of discussion; and statement of commitments made by DOT personnel.

[26] Administrator's Memorandum of May 31, 1985 (instructing agency employees to "be certain (1) that all written comments received from persons outside the Agency (whether

Management Agency.[27] The Department of Agriculture requires all timely written submissions made after publication of a notice of proposed rulemaking to be made available for public inspection, unless the submitter has requested confidentiality and a determination is made that the records can be withheld under the Freedom of Information Act.[28] If they cannot be withheld, the submitter is given an opportunity to withdraw the submission. It is the agency's policy to avoid *ex parte* communications during the rulemaking process; if they do occur, the agency official is to draft a memorandum detailing the communication for inclusion in the rulemaking record.

C. Executive Branch Communications in Rulemaking

Off-the-record communications from within the government -- that is, from the President, his staff, the Office of Management and Budget, or other agencies -- have become an issue in recent years, particularly with respect to discussions between OMB and agencies on draft proposed and final rules

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during or after the comment period) are entered in the public record for the rulemaking, [and] (2) that a memorandum summarizing any significant new factual data or information likely to affect the final decision received during a meeting or other conversations is placed in the public record."). *Id.* at 2.

[27] 44 C.F.R. § 1.6 (1987) (requiring written summary to be placed in informal rulemaking file of all outside communications with "significant information and argument respecting the merits of the proposed rule"). The Solicitor of Labor also announced a policy on the handling of ex parte communications in a memorandum to departmental staff. *See* "Use and Control of Ethylene Oxide", Hearing before Subcommittee on Labor Standards House Committee on Education and Labor, 98th Cong., 1st. Sess. 237-42 (1983).

[28] 7 C.F.R. § 1.27. It is the Department's policy to exclude any late comments from the rulemaking record, although they remain available under the Freedom of Information Act.

under Executive Orders Nos. 12,291 and 12,498.[29] While the analogy between private communications and presidential or other intra-governmental contacts is far from exact, off-the-record communications even among agencies raise concerns about fairness to rulemaking participants and the integrity of the rulemaking record. There is concern that behind-the-scenes intervention by a president or his advisors may frustrate congressional mandates, reduce incentives for regulators to act independently, undermine the APA's rulemaking process, and serve as undisclosed conduits for information supplied by interested private groups.[30] The propriety of OMB contacts with agencies in informal rulemaking has been raised in several cases, but, as yet, no court has dealt explicitly with the constitutional and statutory questions raised by critics of OMB review.[31]

1. *OMB Policy and Practice in Reviewing Agency Rules*

OMB has changed its practice under Executive Order No. 12,291 to accommodate concerns about its communications with agencies during review of agency rulemaking. Early in the implementation of Executive Order No. 12,291, the Reagan Administration issued a memorandum stating:

> Both the public and the agencies should understand that the primary forum for receiving factual communications regarding proposed rules is the agency issuing the proposal, not the Task Force [on Regulatory Relief] or OMB. Factual materials that are sent to the Task Force or OMB regarding proposed regulations should

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[29] These Orders are discussed elsewhere in this Guide. *See* Part I(D), and Part III, Ch. 2, *supra*.

[30] *See* discussion *supra*, Part I(D).

> indicate that they have also been sent to the relevant agency.[32]

The memorandum also stated that, where the President's Task Force on Regulatory Relief or OMB receives or develops factual material that is submitted for agency consideration, it "will be identified as material appropriate for the whole record of the agency rulemaking."[33] The memorandum did not indicate whether the directive applied to oral, as well as written, communications.

The role of OMB in agency rulemaking remained as a source of controversy, however, and in 1986, Congress began to consider legislation to restrict OMB's monitoring role.[34] In June 1986, OMB responded to this pressure by reaffirming certain previously established procedures and by establishing additional procedures for reviews by OMB's Office of Information and Regulatory Affairs (OIRA).[35] In a memorandum to the heads of executive agencies, the OIRA

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[31] *Id.*

[32] Memorandum from David Stockman to Heads of Executive Departments and Agencies, June 11, 1981, *reprinted in* 1990-1991 *Regulatory Program of the United States Government* 618. *See also* Memorandum, Dep't of Justice, Office of Legal Counsel, to OMB, "Contacts between OMB and Executive Branch Agencies Pursuant to Executive Order No. 12,291" (April 24, 1981), *reprinted in part in* Bruff, *Presidential Management of Agency Rulemaking*, 57 Geo. Wash. L. Rev. 533, 580 (1989); 1988 ACUS Recommendations & Reports 527, 582.

[33] Stockman memo, *id.* at 2.

[34] The background of this proposed legislation is described in Bruff, *supra* n.32, 57 Geo. Wash. L. Rev. at 582-83.

[35] Memorandum, Additional Procedures Concerning OIRA Reviews Under Executive Order Nos. 12,291 and 12,498 [Revised], June 13, 1986, from Wendy A. Gramm to Heads of Departments and Agencies Subject to Executive Orders 12,291 and 12,498, *reprinted in* 1990-1991 *Regulatory Program of the United States Government* 605-07.

Administrator announced that OIRA would adhere to the following practices that had been developed under Executive Order No. 12,291:

> 1. Rules must meet statutory requirements, must be based on the agency record and the rulemaking decisions must be made by agency heads. The requirements of Executive Order No. 12,291 apply only to the extent permitted by law.
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> 2. Only the Administrator or Deputy Administrator of OIRA (or someone specifically designated by them) may communicate with a person outside the government on rules being reviewed by OMB.
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> 3. Written materials received from persons outside the government are made available in OMB's public reading room.
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> 4. OMB will advise individuals sending comments on regulatory proposals to send the information to the rulemaking agency.
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> 5. OIRA generally will provide written reasons to the agency when a rule is returned as inconsistent with the President's regulatory principles; and
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> 6. OIRA will issue a report annually on dispositions of rules reviewed under Executive Order No. 12,291.[36]

The OIRA Administrator also established additional new procedures.[37] Upon request OIRA will make available copies of any draft ANPR, NPRM or final rule submitted for review, after publication of the document. OIRA will also make available "all written correspondence" between OIRA and the head of the agency concerning the draft ANPR, NPRM or final rule.[38]

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[36] *Id.* at 605-06 ("Reviews Under Executive Order No. 12,291", "Current OIRA Procedures").

[37] The Administrator stated that the procedures derived from S. 2433, 98th Cong., 2d Sess., reported by the Senate Governmental Affairs Committee, S. Rep. No. 98-576, 98th Cong., 2d Sess. (1984), but not enacted. Administrator

The memorandum also indicated that certain other procedures providing for additional disclosure, which OMB had instituted with respect to EPA rulemaking, would be extended to other agencies, on the request of the head of the agency.[39] The special procedures include advising EPA of all oral communications, such as meetings and telephone calls, that OIRA has with non-government persons relating to EPA rules, and inviting EPA to attend any meetings OIRA holds with such individuals.[40] As of June 1989, four other agencies had requested that these procedures apply to them.[41]

2. *The Judicial Perspective*

Although questions concerning OMB's involvement in informal rulemaking and its off-the-record contacts with agencies during rulemaking have been raised in several cases,

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Gramm said that OMB would be guided by the committee report in interpreting its directives. Memorandum of June 13, 1986, *supra* n. 35, at 606.

[38] *Id.*

[39] *Id.* The EPA procedures are contained in a letter to A. James Barnes, Deputy Administrator, EPA, from Robert P. Bedell, Deputy Administration OIRA May 30, 1985, *reprinted in* 1990-1991 *Regulatory Program of the United States Government* at 619-21. *See also* Clean Air Act, 42 U.S.C. § 7607(d)(4)(B)(ii).

[40] Memorandum, June 13, 1986, *supra* n. 35, at 606. *See also* Memorandum for OIRA Staff, "OIRA Procedures #3," May 30, 1985, *reprinted in* 1990-1991 *Regulatory Program of the United States Government* at 614-17.

[41] The four are the Departments of Labor, Housing and Urban Development, Treasury and Transportation. GAO, Regulatory Review, Information of OMB Review Procedures, GAO/GGD 89-101FS at 17.

courts have thus far declined to deal explicitly with either the statutory or constitutional issues raised by critics of OMB review.[42]

The policy reasons for the courts' reluctance to interfere with intra-governmental communications were forcefully stated by the District of Columbia Circuit in *Sierra Club v. Costle*.[43] The court said:

> The authority of the President to control and supervise executive policymaking is derived from the Constitution; the desirability of such control is demonstrable from the practical realities of administrative rulemaking. Regulations such as those involved here demand a careful weighing of cost, environmental, and energy considerations. They also have broad implications for national economic policy. Our form of government simply could not function effectively or rationally if key executive policymakers were isolated from each other and from the Chief Executive. Single mission agencies do not always have the answers to complex regulatory problems. An overworked administrator exposed on a 24-hour basis to a dedicated but zealous staff needs to know the arguments and ideas of policymakers in other agencies as well as in the White House.[44]

The court accordingly held that it was not unlawful for EPA not to place in the rulemaking file a summary of a policy session involving the President and EPA officials during the post-comment period, since EPA did not base its rule on "information or data" arising from that meeting.[45] In reaching this conclusion, the court referred favorably to an Administrative Conference Recommendation that distinguished policy advice from communications containing material factual information.[46] The court noted that a rule must have factual support in the rulemaking record, and while recognizing the possibility that "Presidential prodding" could produce a different result that was based on information already in the rulemaking record, the court did not "believe that Congress intended that the courts convert informal rulemaking into a rarified technocratic process, unaffected by political considerations or the presence of political power."[47]

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[42] *See* Part I(D)(3).
[43] *Supra* n. 11, 657 F.2d at 404-08.
[44] *Id.*
[45] *Id.* at 407-08.

In 1988, the Fifth Circuit, in *National Grain & Feed Association v. OSHA*,[48] rejected a union contention that OSHA's grain handling standard should be remanded because OMB "displaced the Secretary's congressionally authorized role" by its alleged "off-the-record coercion" of OSHA.[49] Characterizing the unions' brief as telling a "colorful tale of 'the behind-the-scenes evolution of the OSHA standard,'" the court concluded that the record did not support the unions' contention, and ruled that the final rule must "stand or fall on the basis of the record before the agency, not on the basis of some 'secret record' of OMB's."[50]

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[46] *Id.* at 407; ACUS Recommendation No. 80-6, "Intragovernmental Communications in Informal Rulemaking Proceedings," 1 C.F.R. § 305.80-6.

[47] 657 F.2d at 408.

[48] 866 F.2d 717 (5th Cir. 1989).

[49] *Id.* at 729 n. 22.

[50] *Id.*

In a similar case, *Wolfe v. DHHS*,[51] the District of Columbia Circuit held that a public interest group was not entitled to access under the Freedom of Information Act (FOIA) to HHS records showing the dates on which regulatory proposals of the Food and Drug Administration (FDA) were forwarded from FDA to the Secretary of HHS and from there to OMB.[52] Concluding that the requested records were protected by the FOIA exemption for inter- and intra-agency memoranda, the court stated that the "information sought will generally disclose the recommended outcome of the consultative process at each stage of the process, as well as the source of any decision not to regulate."[53] This disclosure, the court held, could reveal policies "prematurely," "chill discussion at a time when agency opinions are fluid and tentative," and "force officials to punch a public time clock."

3. *The Administrative Conference's Recommendations*

In 1980, the Administrative Conference first considered the issue of communications between agencies and other executive branch personnel. The Conference adopted a Recommendation that sought to accommodate the need for internal policy debate with the demands for public participation and requirements of judicial review. First, the Conference concluded that executive departments and agencies should be free to receive written or oral *policy* advice from other executive personnel without having to publicize these contacts.[54] However, when an executive communication contains material *factual* information on a proposed rule, the Conference called on agencies to promptly place copies of documents received (or summaries of oral communications), in the public rulemaking file, and consider giving interested persons an opportunity to respond if the factual material presents important new issues or creates serious conflicts of data.[55] In addition, the Conference advised agencies to alleviate "conduit" concerns by identifying and making public every communication that contains or reflects comments from persons outside the government, regardless of content.[56]

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[51] 839 F.2d 768 (D.C. Cir. 1988) (*en banc*).

[52] *Id.* at 770-73. FDA is an agency within the Department of HHS. In its original decision, 815 F.2d 1527 (D.C. Cir. 1987), the court affirmed the district court's decision ordering disclosure under FOIA. The *en banc* decision, refusing to order disclosure, was split seven to six.

[53] *Id.* at 773-76. *See also Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986) (court avoided issue of OMB involvement in rulemaking, disposing of case on other grounds).

In 1988, the Administrative Conference again addressed the question of executive branch communications during informal rulemaking. In Recommendation No. 88-9,[57] the Conference concluded that:

> 1. When an agency submits a draft proposed or final rule for presidential review, the

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[54] Recommendation No. 80-6, "Intragovernmental Communications in Informal Rulemaking Proceedings," 1 C.F.R. § 305.80-6, ¶ 1. In the Preamble, the Conference stated that agencies other than the one conducting the rulemaking "may have perspectives or expertise not readily available to the rulemaking agency that would enhance the quality of internal debate . . . ."

[55] *Id.* ¶2.

[56] *Id.* *See generally* Verkuil, *Jawboning Administrative Agencies: Ex Parte Contacts by the White House*, 80 Colum. L. Rev. 943 (1980), *reprinted in* 1980 ACUS Recommendations & Reports 511.

[57] "Presidential Review of Agency Rulemaking," 1 C.F.R. § 305.88-9. The Recommendation was based on a report by Professor Harold Bruff. *See* Bruff, *supra* n. 32. Recommendation No. 88-9 is also discussed in Part I(D), *supra*.

submissions and any additional formal analysis submitted should be made public when the proposal or final rule is published or the rulemaking is terminated.[58]

2. An agency should not be required to place in the public file "policy guidance concerning the rulemaking" received from the President or the executive branch; however "official written policy guidance from the officer responsible for presidential review of rulemaking" should be placed in the file once the proposed or final rule is published or the rulemaking is terminated.[59]

3. If an agency receives a communication with new factual information in the presidential review process, the agency should promptly place the communication (or a summary if oral) in the public file.[60]

4. If the agency receives a communication with factual submissions or the views or positions of persons outside the government, the agency should promptly place the communication (or a summary if oral) in the public file.[61]

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[58] Recommendation No. 88-9, ¶ 4 (a). The Recommendation also calls for the disclosure of agendas and summaries of pending or planned rulemaking, and supporting statements submitted for review, which is intended to cover submissions under Exec. Order No. 12,498. *Id.* at ¶ 4(b).

[59] *Id.* at ¶ 5(a).

[60] *Id.* at ¶ 5(b).

[61] *Id.*, ¶ 5(c). The Recommendation states that the official responsible for presidential review "should not allow the process of review to serve as a conduit to the rulemaking agency for unrecorded communications from persons outside the governments." The responsible official should take appropriate steps to guard against this, such as inviting agency representatives to meetings with persons outside the government; in that case, the agency official should prepare a summary of the discussion and promptly place it in the rulemaking file. *Id.*, ¶ 6.

D. Congressional Communications in Rulemaking

Occasionally, parties challenging agency rules have alleged that ex parte communications between members of Congress and agency decisionmakers constituted procedural error justifying invalidation of the rules. However, while courts have held that congressional interference in agency adjudication can cause a denial of procedural due process,[62] courts have not yet found congressional contacts in informal rulemaking to be improper.

In *Sierra Club v. Costle*,[63] the District of Columbia Circuit refused to invalidate an EPA rule because of off-the-record meetings between agency personnel and a United States Senator. Even though the Clean Air Act requires creation of an exclusive record for judicial review, the court concluded that the meetings were not improper:

> The meetings did underscore [the Senator's] deep concerns for EPA, but there is no evidence he attempted actively to use "extraneous" pressures to further his position. Americans rightly expect their elected representatives to voice their grievances and preferences concerning the administration of our laws. We believe it entirely proper for Congressional representatives vigorously to represent the interests of their constituents before administrative agencies engaged in informal general policy rulemaking, so long as individual Congressmen do not frustrate the intent of Congress as a whole as expressed in statute, nor undermine applicable rules of procedure . . .[64]

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[62] *See, e.g., Pillsbury Co. v. FTC*, 354 F.2d 952 (5th Cir. 1966).

[63] *Supra* n. 11.

[64] 657 F.2d at 409.

The court held that to upset a rule based on such ex parte contacts, the challenging party would have to demonstrate that the agency's decision was based upon factors introduced by the ex parte communications that are not relevant to decision under the applicable statute.[65]

E. Intra-agency Communications in Rulemaking

Nothing in the APA bars agency personnel from advising the decisionmaker in informal rulemaking. This contrasts with agency adjudication, in which agency decisionmakers are barred from off-the-record consultations with *anyone* -- including agency investigators or prosecutors -- on a fact in issue.[66] The Attorney General's Manual on the APA explains this different treatment, as follows:

> Not only were the draftsmen and proponents of the bill aware of this realistic distinction between rulemaking and adjudication, but they shaped the entire Act around it. . . . Even in formal rulemaking proceedings subject to sections 7 and 8, the Act leaves the hearing officer entirely

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[65] *Id.* In *D.C. Federation of Civic Ass'ns v. Volpe*, 459 F.2d 1231 (D.C. Cir. 1971), *cert. denied*, 405 U.S. 1030 (1972), the agency's decision to approve construction of a bridge across the Potomac River was influenced by an influential congressman's threats to withhold appropriations for the Washington, D.C. area subway system. The court found the subway appropriations factor was "extraneous" to the statutory criteria that applied to construction of the bridge, and thus not properly considered.

[66] 5 U.S.C § 554(d). Although the APA does prohibit ex parte communications with persons outside the agency in formal rulemaking, it does not bar communications between the decisionmaker and agency personnel, 5 U.S.C. § 557(d). However, inasmuch as in all formal proceedings, the testimony, exhibits, and other papers filed in the proceeding constitute the exclusive record for decision, 5 U.S.C. § 556(e), no extra-record information may be received in either formal adjudication or formal rulemaking. On this point, *see Hercules, Inc. v. EPA*, 598 F.2d 91, 123-24 (D.C. Cir. 1978) (formal rulemaking).

> free to consult with any other member of the agency's staff. In fact, the intermediate decision may be made by the agency itself or by a responsible officer other than the hearing officer. This reflects the fact that the purpose of the rulemaking proceeding is to determine policy. Policy is not made in federal agencies by individual hearing examiners; rather it is formulated by the agency heads relying heavily upon the expert staffs which have been hired for that purpose. And so the Act recognizes that in rulemaking the intermediate decisions will be more useful to the parties in advising them of the real issues in the case if such decisions reflect the views of the agency heads or of their responsible officers who assist them in determining policy.[67]

In *United Steelworkers of America v. Marshall*,[68] the District of Columbia Circuit relied on the distinction between adjudication and rulemaking in refusing to invalidate an OSHA rule because of ex parte communications between the head of OSHA and attorneys on the agency's rulemaking staff. Finding no statutory basis for restricting such communications, the court rejected the petitioners' claim of procedural error, stating:

> Rulemaking is essentially an institutional, not an individual, process, and it is not vulnerable to communication within an agency in the same sense as it is to communication from without. In an enormously complex proceeding like an OSHA standard setting, it may simply be unrealistic to expect an official facing a massive, almost inchoate, record to isolate herself from

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[67] Attorney's General Manual on the Administrative Procedure Act 15 (1947), *reprinted in* ACUS Federal Administrative Procedure Sourcebook. For an excellent treatment of separation of functions in agency proceedings, *see generally* Asimow, *When the Curtain Falls: Separation of Functions in the Federal Administrative Agencies*, 81 Colum. L. Rev. 759 (1981).

[68] *Supra* n. 6.

> the people with whom she worked in generating the record.[69]

The District of Columbia Circuit again confronted the issue of staff communications with the agency decisionmaker in *National Small Shipments Traffic Conference, Inc. v. ICC*.[70] The court refused to invalidate a rule on the basis that staff had been actively involved in the decisionmaking process, emphasizing that neither a federal statute nor due process "imposes a general separation-of-function requirement on informal rulemaking by an agency."[71] The ICC was therefore free to lift its restrictions on staff participation.

The court also addressed the issue of the agency's handling of staff recommendations. Petitioners argued that staff evaluations critical of the study relied on by the ICC in its decision had been "suppressed." The court rejected this contention, stating:

> [P]etitioners do have a legal right that their comments reach Commission members in at least summary form, and that those comments be considered before final action is taken. Neither the APA nor the due process clause, however, accords similar treatment to staff evaluations that move beyond a mere summary of record comments to express the independent judgments of subordinate agency personnel. An agency is free to structure its internal policy debate in any manner it deems appropriate. Mid-level managers may therefore filter out the evaluations of lower-level personnel if they so

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[69] 647 F.2d at 1216.
[70] 725 F.2d 1442 (D.C. Cir. 1984).
[71] *Id.* at 1448.

> choose, so long as relevant record comments are not eliminated in the process as well.[72]

To assure itself of the accuracy or completeness of rulemaking staff representations, as well as to increase public confidence in the fairness of the process, an agency should consider placing in the record any documents written by the staff that summarize or characterize the information in the rulemaking record. This procedure can provide a check to minimize the chances of distortion of public comments and other information in the record by staff members who may have become unduly committed to a particular point of view.

F. Communications with Consultants

Agencies sometimes use the services of outside consultants in developing rules or supporting analyses, particularly in rulemakings involving questions of science or technology as to which the agency needs added expertise. The tasks consultants are asked to perform vary, but they include testifying as witnesses, conducting research, summarizing and evaluating data in the record, and helping draft portions of the final rule and its rationale.[73]

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[72] *Id.* at 1451 (citations omitted). In any event, the court rejected the argument on the merits, finding that the evidence established that the Commission members were made fully aware of the comments, particularly those criticizing the agency's proposed action.

[73] *Id.* For a discussion of the use of consultants in the preparation of regulatory analysis documents, *see* ACUS Recommendation No. 85-2, "Agency Procedures for Performing Regulatory Analysis of Rules," 1 C.F.R. § 305.85-2. The use of consultants by federal agencies in rulemaking activity is discussed in General Accounting Office, Briefing Report to Congressional Requesters, Occupational Safety and Health, OSHA Contracting for Federal Rulemaking Activities, June 1989, GAO/HRD-89-102 BR.

Ex Parte Communications

Decisionmakers' use of consultants' reports and analyses that were not placed in the rulemaking record was challenged in *United Steelworkers of America v. Marshall*.[74] The District of Columbia Circuit concluded that, even though the consultants had testified publicly in favor of the proposed rule and later analyzed the public record for the agency decisionmaker, they were the "functional equivalent' of agency staff and, therefore, not subject to ex parte or separation-of-function restraints.[75] The opinion intimated, however, that had the consultants introduced significant new information in their reports, the court would have had greater difficulty upholding the rule.[76]

In *National Small Shipments*,[77] the court, again relying on *Steelworkers*, held that "in the informal rulemaking context private technical consultants may assist the agency in analyzing the record without running afoul of the prohibition on ex parte contacts."[78] Although some bureaucratic "disarray" surrounded the individual's contract with the agency in that case, the court held that a consultancy did exist, thus making the individual "an insider" for purposes of the ex parte contacts rule.[79]

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[74] *Supra* n. 6.

[75] *Id.*, 647 F.2d at 1218-20.

[76] *Id.* at 1220. In a related case, *Lead Industries Ass'n v. OSHA*, 610 F.2d 70 (2d Cir. 1979), the Second Circuit held that consultants' reports in the lead rulemaking were exempt from disclosure under the Freedom of Information Act as internal agency communications.

[77] *Supra* n. 70.

[78] 725 F.2d at 1449-50.

[79] *Id.*

PART III: INFORMAL RULEMAKING IN PRACTICE

CHAPTER 7

THE FINAL RULE

Between the end of the comment period and a final rule's publication in the Federal Register, there are a number of topics that an agency may need to consider in addition to decisions on the substance of the rule. Topics discussed in the first section of this chapter include the importance of time limits, interagency coordination where necessary, effective dates for rules, and disqualification of decisionmakers.

The chapter then addresses the statement of basis and purpose (commonly referred to as the "preamble") required by the Administrative Procedure Act for a final rule. The courts have underscored the necessity that such a statement adequately articulate the reasons for the agency's decisions.

Finally, this chapter discusses several technical rules, including Office of the Federal Register requirements, that must be complied with in publishing the rule.

A. Issues for Agency Consideration

1. *Time Limits for Agency Action*

The APA does not require agencies to act on rulemaking proposals within a prescribed time after the end of public proceedings.[1] Agency rulemaking activities are, however, often subject to deadlines. Enabling statutes have, with increasing frequency, imposed deadlines for issuing rules, and in some cases, for completing various rulemaking steps.[2] In addition, courts have issued orders containing rulemaking deadlines based either on the enabling statute or on a finding that the agency has not completed rulemaking "within a reasonable time."[3] An agency should, therefore, be keenly aware of the importance of prompt completion of rulemaking, both for good management and in view of legal constraints imposed on agencies.

Numerous delays can occur in the latter stages of rulemaking. The record, often lengthy, must be assessed by the staff and summarized for decisionmaking. Recommendations must be prepared. Different disciplines may become involved, and coordination with other agencies and OMB review will typically take place. Sometimes, internal policy disputes arise at the deliberative stage. All of these, as well as other factors, may delay the issuance of a final rule.

Where the enabling statute imposes a time limit on agency action, the agency should obviously strive to meet the congressional deadline. However, even in the absence of a statutory time limit, many agencies find it helpful to set their own schedules for completion of the various rulemaking steps, including the deliberative process. Not only do these schedules provide the agency a practical yardstick for determining whether its rulemaking is making satisfactory progress towards completion,[4] but in some cases, courts have accepted such schedules as representing good faith efforts by the agency to complete its rulemaking within a "reasonable" time.[5] Some federal agencies have established formal case tracking systems and set time limits to speed up their proceedings.[6] Although these systems have not generally been set up for rulemaking, a similar system might be useful in such context.

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[1] 5 U.S.C. § 555(b) does require agencies to conclude matters "within a reasonable time," and courts are authorized to compel agency action "unreasonably delayed," 5 U.S.C. § 706(1). *See* discussion *infra*, Part IV, Ch. 3.

[2] For examples of these enabling statutes, *see* discussion *supra*, Part I(C).

[3] Court suits to compel agency actions are discussed more fully *infra*, Part IV, Ch. 3.

2. Interagency Coordination and Review

Often several agencies have jurisdiction over a particular issue or area, or over different but related areas. The Federal Trade Commission provides a good illustration of this phenomenon. It shares with the Antitrust Division of the Department of Justice the authority to prosecute certain antitrust violations.[7] In the food and drug area, the FTC polices unfair or deceptive product advertising by sellers, while the Food and Drug Administration prescribes labeling standards for the products.[8] A similar overlap of jurisdiction exists between FTC regulation of advertising and the FCC's regulation of the broadcast media.[9] Another example is the overlap of the jurisdiction of several federal agencies in the area of pesticides regulation.[10] EPA and the Department of Agriculture have jurisdiction over pesticide application, while OSHA is authorized to regulate hazards involved in pesticide manufacture. Similarly, numerous agencies have authority to regulate asbestos hazards.[11]

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[4] The Administrative Conference has recommended that agencies adopt time limits in agency proceedings, either by announcing schedules for particular agency proceedings or by adopting general timetables for dealing with categories of the agency's proceedings. Recommendation No. 78-3, "Time Limits on Agency Actions," 1 C.F.R. § 305.78-3, ¶3. *See also* Senate Comm. on Governmental Affairs, 95th Cong., 1st Sess., Study on Federal Regulation, V. IV: Delay in the Regulatory Process 132-152 (1977) (concluding that agency-set time limits are useful tools for reducing delay).

[5] *See, e.g., Oil Chemical and Atomic Workers Int'l Union v. Zegeer*, 768 F.2d 1480 (D.C. Cir. 1985).

[6] *See* Garner, *Management Control in Regulatory Agencies: A Modest Proposal for Reform*, 34 Admin. L. Rev. 465, 475-79 (1982) (discussing the NLRB and ICC).

[7] The FTC has concurrent jurisdiction with the Department of Justice in proceedings against price discrimination, exclusive

Where overlapping or related jurisdiction exists, it is clearly essential that the agencies involved consult with one another at the earliest possible stage in the rulemaking proceedings. In some cases, statutory provisions mandate

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dealing, acquisitions of stock or assets, and interlocking directorates that are prohibited by the Clayton Act. 2 Trade Reg. Rep. (CCH) ¶ 8550.

[8] *See* Working Agreement Between FTC and Food and Drug Administration (June 9, 1954), 3 Trade Reg. Rep. (CCH) ¶ 9850.

[9] *See* Liaison Agreement Between Federal Communications Commission and the Federal Trade Commission (Apr. 27, 1972), 3 Trade Reg. Rep. (CCH) ¶ 9852.

[10] Overlapping jurisdiction or the existence of "gray" areas of jurisdiction can sometimes lead to disputes and litigation. *See Organized Migrants in Community Action, Inc. v. Brennan*, 520 F.2d 1161 (D.C. Cir. 1975) (OSHA and EPA jurisdiction over pesticide application).

[11] EPA has jurisdiction to control asbestos under the Clean Air Act, 42 U.S.C. §§ 7401 *et seq.*, Clean Water Act, 33 U.S.C. §§ 1251 *et seq.*, and Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601 *et seq.*, which includes the Asbestos Hazard Emergency Response Act (AHERA). OSHA has jurisdiction over workplace asbestos hazards, and the Consumer Products Safety Commission has responsibility for asbestos hazards in consumer products. *See* Final Rules, Occupational Exposure to Asbestos, OSHA, 51 Fed Reg. 22,612, 22,613-14 (1986).

such consultation. The Federal Insecticide, Fungicide and Rodenticide Act, for example, requires that EPA submit its proposed rules to the Department of Agriculture for comment.[12] The Toxic Substances Control Act contains a detailed procedure under which EPA coordinates with the other federal agencies that have potential jurisdiction to regulate the substance in question.[13] In other cases, agencies have set up informal groups to coordinate implemention of their parallel, and often overlapping, regulatory responsibilities. An important example was the Interagency Regulatory Liason Group (IRLG), formed by OSHA, EPA, CPCS, FDA, and the Department of Agriculture to coordinate their approaches to regulation of certain hazardous chemicals.[14]

Agency officials should be attentive to statutory requirements for interagency coordination during rulemaking.

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[12] 7 U.S.C §§ 136, 136w. *See* Proposed Rule, Special Reviews of Pesticides; Criteria and Procedures, EPA, 50 Fed. Reg. 12,188, 12,200-03 (1985). In its proposal, EPA published the Department of Agriculture's comments on the proposal, as well as EPA's responses to the comments. *Id.*

[13] 15 U.S.C. § 2608. The TSCA procedures EPA and OSHA followed in determining which agency would regulate methylenedianiline (MDA) are described in the preamble to OSHA's proposed standard on MDA. Proposed Rule, Occupational Exposure to MDA, OSHA, 54 Fed. Reg. 20,672, 20,672-73 (1989).

[14] *See* Merrill, *Federal Regulation of Cancer Causing Chemicals*, 1982 ACUS Recommendations & Reports, V. II, 21, 176-78. *See also* Final Rule, Asbestos, *supra* n. 11, 51 Fed. Reg. at 22,614 (referring to Federal Asbestos Task Force, established in June 1983, to coordinate federal regulatory actions with regard to asbestos).

ACUS has recommended the increased use of interagency groups in the area of biotechnology regulation. Recommendation No. 89-7, "Federal Regulation of Biotechnology," 1 C.F.R. § 305.89-7. *See also* Shapiro, *Biotechnology and the Design of Regulation*, 17 Ecology L. Q. 1 (1990).

Whether coordination is legally required, or has been undertaken as a matter of agency discretion and good management, the agency's posture will be much better in relation to other agencies, the courts and the public if interagency coordination and review begins early and continues throughout the rulemaking process.

3. *The Final Regulatory Analysis and OMB Review*

Under Executive Order No. 12,291, federal agencies conducting rulemakings must prepare a final regulatory impact analysis and submit the analysis and the draft final rule to OMB for review. The submission must occur at least 30 days prior to publication of a *major* rule as a final rule; the agency must submit the draft final version of other rules (and the final regulatory analysis if one has been prepared) to OMB at least 10 days prior to publication.[15] An earlier chapter discusses the content of the regulatory analysis.[16] In the final regulatory analysis, the agency typically will incorporate the earlier analysis, making appropriate changes in response to information received in public proceedings after the initial analysis was prepared. Absent a controlling statutory deadline, an agency is required by Executive Order No. 12,291 to refrain from publishing a final analysis or final rule until it has responded to OMB's views on a final analysis or rule.[17]

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[15] Exec. Order No. 12,291, §§ (3)(c)(2) and (3), *reprinted in* 5 U.S.C. § 601 note.

[16] *Supra*, Part III, Ch. 2(A)(2).

[17] Exec. Order No. 12,291, § 3(f)(2). The agency must refrain from publishing the final analysis or rule if the agency receives notice that OMB "intends to submit views" with respect to the analysis or rule. *Id.*

The rulemaking agency must also keep in mind its responsibility to obtain appropriate clearance for information collection requirements from OMB under the Paperwork Reduction Act.[18] In particular, under the Act, the agency is required in publishing its final rule to respond to OMB's comments, or explain why it rejected OMB's comments.[19] In addition, the agency must comply with legal requirements for preparing a final environmental impact analysis[20] and a final regulatory flexibility analysis,[21] as well as analyses as required under executive orders on federalism, the "takings" clause of the U.S. Constitution, and the family.[22]

4. *Determining the Effective Date for the Final Rule*

With narrow but significant exceptions,[23] the APA provides that agency rules may not be made effective until 30 days after publication in the Federal Register.[24] The delayed effective date provision was included to give persons affected by the rule a reasonable time to comply with the rule or take other action.[25] Such action might include petitioning for exemption from rule requirements or pursuing judicial review of the rule. The delayed effective date provision also gives the agency an opportunity to modify the rule to avoid previously unforseen and undesirable consequences of its rule.

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[18] These requirements are discussed in detail, *supra*, Part III, Ch. 2(B).

[19] 44 U.S.C. § 3504(h)(3); 5 C.F.R. 1320.13(e). If the agency has substantially changed information collection requirements from the NPRM, it must submit the final rule to OMB for approval at least 60 days before Federal Register publication. 5 C.F.R. 1320.13(g)(2).

[20] Discussed *supra*, Part II, Ch. 3(C); Part III, Ch. 2(E).

[21] Discussed *supra*, Part III, Ch. 2(C).

[22] *Id.*, subs. (D).

[23] These exceptions are discussed *supra*, Part II, Ch. 1(D)(4)(d).

[24] 5 U.S.C. § 553(d).

[25] Attorney General's Manual on the Administrative Procedure Act 36 (1947), *reprinted in* ACUS Federal Administrative Procedure Sourcebook.

Determining the effective date of rules has been complicated by requirements for additional review of rules. Since Executive Order No. 12,291 establishes no deadline for completion of OMB review under that order, agencies cannot set a precise effective date until the review is completed. In addition, the Paperwork Reduction Act gives OMB 60 days after publication of a final rule to disapprove any collection of information requirement in the agency's rule.[26] Thus, it is possible that critical aspects of proposed rules may not be made effective until at least 60 days following publication of the rule. Of course, if OMB's objections are met, this requirement will not delay the rule's taking effect.

While the APA sets a minimum delayed effective date for agency rules, an agency may, in its discretion, set a more delayed effective date for some or all of the requirements of a rule.[27] A longer period would normally be appropriate where, for example, the obligations imposed are onerous or would involve considerable expenditure of time and money, or for some other sound reason. In some cases, courts upholding the feasibility of a regulatory provision have relied on the fact that the agency has provided a lengthy delayed effective date, thus facilitating compliance.[28] An agency's discretion to extend the time for compliance would, of course, be constrained by public policy considerations; for example, where the rule in question is intended to protect the public health.[29] Some enabling statutes limit agency discretion in delaying effective dates.[30]

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[26] 44 U.S.C. § 3504(h)(5).

[27] Similarly, the agency may decide to set different effective dates for various portions of rule. Thus, for example, under the Federal Railroad Administration's rules on random drug testing published on November 21, 1988, staggered effective dates were set as follows: railroad random testing program submission - June 10, 1989; Transportation Workplace Drug Testing Programs implementation - July 19, 1989; and implementation of random testing and prohibition of non-medical drug use programs - November 20, 1989. Dep't. of Transportation, Federal Railroad Administration, Final Rule, Random Drug Testing, 53 Fed. Reg. 47,102 (1988).

Another issue is the validity of an agency rule with a retroactive effective date. Under the APA, the term "rule" is defined as an agency statement of "general or particular applicability and *future effect*."[31] Where agency policy is enunciated in the course of adjudication, the courts have held that retroactive application is permitted "unless the inequities produced by retroactive application are not counterbalanced by sufficiently significant statutory interests."[32] However, where the policy is embodied in a legislative rule, different considerations apply. In *Bowen v. Georgetown University Hospital*,[33] the Supreme Court held that an HHS rule on recovery of medicare costs with a retroactive effective date was invalid. The majority based its decision on the provisions of the Medicare statute, which it read expressly to preclude retroactive rulemaking in the context of the case.[34] The Court's opinion includes language suggesting that retroactive rulemaking may only be permissible where Congress has expressly authorized it; this language is presumably dicta, since the statute in issue expressly ruled out such rulemaking. Moreover, the case involved a rule that had only retroactive, and no prospective, effect.

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[28] *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1278 (D.C. Cir. 1980), *cert. denied*, 453 U.S. 913 (1981) ("The extremely remote deadline at which the primary smelters are to meet the final permissible exposure limit is perhaps the single most important factor supporting the feasibility of the standard".)

[29] *See Industrial Union Department v. Hodgson*, 499 F.2d 467, 481 (D.C. Cir. 1974) (reversing OSHA's 4-year delayed effective date for lower permissible exposure limit for asbestos).

[30] *See, e.g.*, National Traffic & Vehicle Safety Act of 1966, 15 U.S.C. § 1392(c) (requiring that rules be effective within one year of issuance). NHTSA, in issuing its Occupant Crash Protection Final Rule in 1984 on remand from the Supreme Court in *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983), found "good cause" for delaying the effective date for more than one year. Dep't. of Transportation, National Highway Traffic Safety Administration, Final Rule, Occupant Crash Protection, 49 Fed. Reg. 28,962, 29,009 (1985) (lead time necesssary to provide car manufacturers with "effective choice" about kind of automatic restraint installed in their cars).

[31] 5 U.S.C. § 551(4) (emphasis added).

In his concurrence, Justice Scalia went even further, stating that retroactive application of a rule was contrary to the APA itself.[35] He distinguished, however, "secondary retroactivity" (that is, a rule with "exclusively future effect . . . which 'affects' past transactions"[36]); a rule with "secondary retroactivity," Justice Scalia stated, may be valid under the APA, if "reasonable."[37]

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[32] *Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750 756 (D.C. Cir. 1987), *aff'd on other grounds*, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 109 S. Ct. 468 (1988), discussed *infra*.

[33] 109 S.Ct. 468.

[34] *Id.* at 475.

[35] *Id.* (concurring opinion).

[36] *Id.* at 477.

[37] *Id. Accord: Chemical Waste Management, Inc. v. EPA*, 869 F.2d 1526, 1535-37 (D.C. Cir. 1989) (holding EPA regulation prospective and therefore valid because it applies only if proscribed action occurs after the rule was promulgated, despite impacts on past activities).

The dicta in *Georgetown Hospital* requiring express statutory authority would appear to be a departure from cases holding that retroactivity in rulemaking *may* be permissible where it would not be "manifestly unjust"[38] or where a balance of factors favors it. These factors include

> 1. Whether the rule is an abrupt departure from well-established practice or it fills a void in an unsettled area of law;
>
> 2. The extent of reliance on the former rule;
>
> 3. The degree of burden which retroactivity could impose; and
>
> 4. The statutory interest in applying a new rule despite the reliance of a party on the old standard.[39]

The issue remains in some flux.[40]

5. *Disqualification of Decisionmakers*

The acceptability of rules and, indeed, the repute of the administrative process, may be seriously impaired if the judgment of agency officials who determine the content of rules is believed to have been tainted by conflicts of interest, inflexible prejudgment of pertinent facts, or manifestations of hostility towards particular interests. The propriety of agency officials' participation in rulemaking has been an issue in a few cases. In each case, there were allegations that the agency official was biased or had prejudged the issues in the proceeding, and the court was asked to disqualify the official from further participation or to invalidate the final agency rule. The decisions in these cases firmly establish that the disqualification standard applicable to adjudication is inappropriate for informal rulemaking: rather, those seeking disqualification in the rulemaking context must make a "clear showing . . . [of] an unalterably closed mind."[41]

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[38] *See, e.g., Greene v. U.S.*, 376 U.S. 149, 160 (1964); *Coe v. Secretary of HEW*, 502 F.2d 1337, 1339 (4th Cir. 1974).

[39] *See, e.g., Maxcell Telecom Plus, Inc. v. FCC*, 815 F.2d 1551, 1554-55 (D.C. 1987). These factors originated in *Retail, Wholesale Dep't. Store Union v. NLRB*, 466 F.2d 380, 390 (D.C. Cir. 1972), a case involving adjudication rather than rulemaking. *Cf. NRDC v. Thomas*, 838 F.2d 1224, 1244 (D.C. Cir.), *cert. denied sub nom. Alabama Power Co. v. Thomas*, 109 S. Ct. 219 (1989) (stating that these factors applied in determining whether to apply a rule retroactively; case involved "secondary" retroactivity).

[40] *See* Luneburg, *Retroactivity and Administrative Rulemaking*, 1990 Duke L.J. (forthcoming)

This standard was first enunciated in *Association of National Advertisers v. FTC*,[42] in which the District of Columbia Circuit considered whether certain statements of the FTC Chairman warranted his disqualification from participating in a rulemaking proceeding conducted under the Magnuson-Moss Warranty -- Federal Trade Commission Improvements Act.[43] The court refused to disqualify the Chairman for remarks made prior to the proceeding. After rejecting a characterization of Magnuson-Moss Act rulemaking as "quasi-adjudicative," the court concluded that the disqualification standard applicable to adjudication is not appropriate for rulemaking because of the different nature of the factual conclusions reached in each type of proceeding.[44]

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[41] *Association of Nat'l Advertisers v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979), *cert. denied*, 447 U.S. 921 (1980).

[42] *Id.*

[43] 15 U.S.C. § 57a.

[44] In so concluding, the court relied upon Professor Kenneth Culp Davis' distinction between "legislative" and "adjudicative"

The court also emphasized the differences in the roles of rulemakers and adjudicators. The majority opinion stated that the "view of a neutral and detached adjudicator is simply an inapposite role model for an administrator who must translate broad statutory commands into concrete social policies. If an agency official is to be effective, he must engage in debate and discussion about the policy matters before him."[45] The same

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facts. The court stated: "[t]he factual predicate of a rulemaking decision substantially differs in nature and in use from the factual predicate of an adjudicatory decision. The factual predicate of adjudication depends on ascertainment of 'facts concerning the immediate parties--who did what, where, when, how, and with what motive or intent.' [citing 1958 edition of Professor Davis' treatise]. By contrast, the nature of legislative fact is ordinarily general, without reference to specific parties. . . ." *Id.* at 1168-69.

[45] *Id.* at 1168-69. Judge Leventhal, in a concurring opinion, contrasted the roles of adjudicator and rulemaker as follows:

> One can hypothesize beginning an adjudicatory proceeding with an open mind, indeed a blank mind, a tabula rasa devoid of any previous knowledge of the matter. In sharp contrast, one cannot even conceive of an agency conducting a rulemaking proceeding unless it had delved into the subject sufficiently to become concerned that there was an evil or abuse that required regulatory response. It would be the height of absurdity, even a kind of abuse of administrative process, for an agency to embroil interested parties in a rulemaking proceeding, without some initial concern that there was an abuse that needed remedying, a concern that would be set forth in the accompanying statement of the purpose of the proposed rule.

standard was subsequently applied in *Lead Industries Ass'n v. EPA*[46] and *United Steelworkers of America v. Marshall*.[47]

The Administrative Conference studied the issues raised by the *Association of National Advertisers* decision and recommended[48] that disqualification for bias in rulemaking be limited to prejudgments of particular "adjudicative" or "specific" facts, where it may be inferred from the particular statutory framework, agency procedural choices, or other special circumstances that the agency's determination of those facts is to be based on an evidentiary record developed in the proceeding.[49]

> In its administrative setting an agency's effort is not limited to one type of activity. Investigation and policy-making are integral to the total function just as much as decisionmaking. It is appropriate and indeed mandatory for agency heads and staff to maintain contacts with industry and consumer groups, trade associations and press, congressmen of various persuasions, and to present views in interviews, speeches, meetings, conventions, and testimony . . . .

Id. at 1176.

[46] 647 F.2d 1130, 1179 (D.C. Cir. 1980), *cert. denied*, 449 U.S. 1042 (1980).

[47] *Supra* n. 28, 647 F.2d at 1208-10.

[48] Recommendation No. 80-4, "Decisional Officials' Participation in Rulemaking Proceedings," 1 C.F.R. § 305.80-4. The Recommendation is based on Strauss, *Disqualification of Decisional Officials in Rulemaking*, 80 Colum. L. Rev. 990 (1980), *reprinted in* 1980 ACUS Recommendations & Reports 375.

[49] The concept of "specific fact" was discussed in the *Association of Nat'l Advertisers* majority opinion, and the Conference's consultant explains it as follows:

On the other hand, the Conference recognized that a rulemaking proceeding should be conducted with decorum and respect for the interests of all concerned, and agency officials should avoid intemperate expression or other behavior suggestive of an irrevocable commitment to a predetermined outcome of the proceeding. This does not mean, however, that agency officials may not express judgments on factual issues based on previous experience or on information received during a proceeding. Nor does it suggest that officials may not act upon nor voice opinions in interchanges with committees of Congress, other administrative bodies, the public, and regulated groups; such activity is desirable conduct for administrators, not an abnormality to be shunned.[50]

> A characteristic of "specific facts" is that they do not require judgment, prediction, or policy orientation for determination. Although not "adjudicative facts" in the strictest sense -- involving neither specific individuals nor historic circumstances -- specific facts by hypothesis share the characteristics of concreteness and provability that make trial-type procedures superior for their determination. Determining the ductile strength of a given steel alloy differs from making a judgment about the anticompetitive impact of joint ownership of television stations and newspapers, in just this way. Facts about ductility *can* be developed through evidentiary hearings, and *are* severable from policy issues . . . .

Strauss, *id.* at 1043 (emphasis in original).

The Conference also concluded that an agency should be obliged to consider disqualifying an agency member or decisional employee only after it has been established in the proceeding that adjudicative or specific facts can be severed from policy and require resolution on an evidentiary record. Recommendation No. 80-4, *supra* n. 48, at ¶ C.

[50] Recommendation No. 80-4, ¶ D. On the issue of contacts between agency rulemaking officials and Congress and

The Final Rule

Perhaps of greater significance to agency rulemakers is disqualification sought on the basis of an alleged conflict of interests. Under Executive Order No. 12,674[51] and regulations of the Office of Government Ethics,[52] federal agencies are required to regulate employee conduct with respect to conflicts of interest. Moreover, it is a criminal offense for a government official to participate personally and substantially in a "particular matter in which, to his knowledge, he, his spouse, minor child, partner, organization in which he is serving . . . or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment, has a financial interest."[53]

In general, the cited provisions and the requirements for employee reports deal with financial or associational interests of a commercial or financial character. Agency rules often do not deal with possible conflicts arising from either prior employment or activities on behalf of political, religious, civic, or other organizations. However, the Administrative Conference recommends that agency regulations provide for recusal (*i.e.*, withdrawal from participation) if a significant non-

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members of the public, *see Sierra Club v. Costle*, 657 F.2d 298 (D.C. Cir. 1981), *discussed supra*, Part III, Ch. 6.

[51] 54 Fed. Reg. 15159 (1989), *as modified*, 55 Fed. Reg. 42547 (1990). This Executive Order superseded Executive Order No. 11,222, which had been the basis of regulations issued by the Office of Personnel Management and widely adopted by federal agencies.

[52] 5 C.F.R. Part 735 (1990) (to be transferred to 5 C.F.R. Part 2635, pursuant to the Office's new status as a separate executive agency).

[53] 18 U.S.C. § 208. The term "particular matter" has been interpreted by the Department of Justice to include rulemaking, *see* Memorandum Opinion for the Chief Counsel, Food and Drug Administration, 2 Op. Off. Legal Counsel 151, 155 (1978).

financial interest of the official is likely to be substantially affected by the outcome of the proceeding, and for "cooling-off" periods for new officials with respect to participation in proceedings affecting prior employers, clients, or other financial interests.[54] The agency should make clear that these regulations are aids to agency self-management, and are not intended to expand the scope of judicial review of rulemaking proceedings. Thus, although the Administrative Conference takes a narrow view of the circumstances in which an agency should be obliged to disqualify a rulemaking official, it believes agencies should consider formulating standards for officials' conduct more exacting than the minimum legal standards.

B. The Statement of Basis and Purpose

Section 553(c) of the APA provides that, after consideration of relevant material presented in the rulemaking, "the agency shall incorporate in the rules adopted a concise statement of their basis and purpose."[55] A contemporaneous interpretation of the statement of basis and purpose requirement in the APA was that it was "not intended to require an elaborate analysis of rules or of the detailed considerations upon which they are based but [rather] is designed to enable the public to obtain a general idea of the purpose of, and a statement of the basic justification for, the rules."[56] Certainly a major purpose of the statement of basis and purpose, which constitutes most of what is commonly referred to as "the preamble" to a rule, is to inform the public of the supporting reasons and purposes of the final rule. Agencies often use the statement to advise interested persons how the rule will be applied, to respond to questions raised by comments received during the rulemaking, and as a "legislative history" that can be referred to in future applications of the rule.

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[54] Recommendation No. 80-4, ¶ B.3.

[55] 5 U.S.C § 553(c).

[56] Legislative History of the APA, S. Doc. No. 248, 79th Cong., 2d Sess. 225 (1947); *see also* Attorney General's Manual on the Administrative Procedure Act 32 (1947), *reprinted in* ACUS Federal Administrative Procedure Sourcebook.

Although the original purpose for including the statement of basis and purpose requirement in the APA may have been to inform the public, it has also become the primary document judges turn to in deciding the validity of challenged rules. What reviewing courts have come to expect of statements of basis and purpose is stated in the following language from the District of Columbia Circuit's opinion in *Automotive Parts & Accessories Association v. Boyd*:[57]

> [I]t is appropriate for us . . . to caution against an overly literal reading of the statutory terms "concise" and "general." These adjectives must be accommodated to the realities of judicial scrutiny, which do not contemplate that the court itself will, by a laborious examination of the record, formulate in the first instance the significant issues faced by the agency and articulate the rationale of their resolution. We do not expect the agency to discuss every item or opinion included in the submissions made to it in informal rulemaking. We do expect that, if the judicial review which Congress has thought it important to provide is to be meaningful, the "concise general statement of . . . basis and purpose" mandated by Section 4 [now 5 U.S.C. §553] will enable us to see what major issues of policy were ventilated by the informal

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[57] 407 F.2d 330 (D.C. Cir. 1968).

> proceedings and why the agency reacted to them as it did.[58]

It has also been suggested that the statement of basis and purpose serves a critical, self-education purpose for the agency.[59] Thus, in preparing the explanation for the rule, the agency has an opportunity to confront its planned action in detail, including all the steps in its reasoning process, and to judge whether the action embodied in the draft statement of basis and purpose is indeed one that it wishes to take.

The Supreme Court reinforced the importance of the statement of basis and purpose in 1983 in *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*[60] There, the Court vacated the National Highway Traffic Safety Administration's rule rescinding the agency's earlier rule requiring passive restraints in automobiles. While making it clear that it was judging the rule under an "arbitrary and capricious" standard of review, which does not permit the Court to substitute its judgment for that of the agency, the Supreme Court elaborated on the process an agency must follow to avoid an "arbitrary or capricious" finding.[61] "The Agency must examine the relevant data and articulate a satisfactory explanation for its action," the Court said, including "a 'rational connection between the facts found and the choice made.'"[62] An agency decision could be arbitrary and capricious if the agency relied on factors Congress did not intend be considered, "entirely failed" to consider an important aspect of the problem, or offered an explanation for its decision that "runs counter to the evidence" or that was "so implausible" that it could not be ascribed to a difference of view or the product of agency expertise.[63] The Supreme Court overruled the agency rescission because it gave "no consideration whatever" to modifying the standard to require airbags only.[64] "At the very least," the Supreme Court said, "this alternative way of achieving the objectives of the Act [the use of airbags] should have been addressed and adequate reasons given for its abandonment."[65]

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[58] *Id.* at 338.

[59] *See, e.g., Dry Color Mfrs. Ass'n v. Dep't of Labor*, 486 F.2d 98, 105 (3d Cir. 1973) (requirement for a statement of basis and purpose "provides an internal check on arbitrary agency action by insuring that prior to taking action an agency can clearly articulate the reasons for its decision").

[60] 463 U.S. 29 (1983).

[61] *Id.* at 41-43.

The *State Farm* decision involved the rescission of a rule, but the Supreme Court held that the same standard of review would pertain to both rescission and promulgation of rules.[66] This decision has been followed by both the Supreme Court and the courts of appeals since 1983. Thus in 1986, the Supreme Court in *Bowen v. American Hospital Association*[67] vacated HHS rules on the health care for handicapped infants, saying, "Agency deference has not come so far that we will uphold regulations whenever it is possible to 'conceive a basis' for administrative action."[68] "Our recognition of Congress' need to vest administrative agencies with ample power to assist in the difficult task of governing a vast and complex industrial nation," the Court said, "carries with it the correlative responsibility of the agency to explain the rationale and factual basis for its decision even though we show respect for the agency's judgment in both."[69]

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[62] *Id.* at 43, quoting *Burlington Truck Lines, Inc. v. U.S.*, 371 U.S. 156 (1962).
[63] *Id.*
[64] *Id.* at 51.
[65] *Id.* at 48.
[66] *Id.* at 41-42.
[67] 476 U.S. 610, 106 S. Ct. 2101 (1986).
[68] 106 S. Ct. at 2112.

Since *State Farm*, numerous courts of appeals have considered the adequacy of agencies' statements of basis and purpose for rules, and in some cases have vacated agency rules because the statement was inadequate.

In *Independent U.S. Tanker Owners Committee v. Dole*,[70] for example, the District of Columbia Circuit vacated a DOT rule because the statement of reasons was inadequate.[71] Referring to the APA requirements, the court said that the statement "need not be an exhaustive detailed account of every aspect of the rulemaking proceedings,"[72] but "such a statement should indicate the major issues of policy that were raised in the proceedings and explain why the agency decided to respond to these issues as it did, particularly in light of the statutory objectives that the rule must serve."[73] The court concluded that the Secretary of Transportation had failed to give an adequate account of how the rule served the statutory objectives and "why alternative measures were rejected in light of them."[74] The court said that while the Secretary was free to consider non-statutory factors, "she is not free to substitute new goals in place of the statutory objectives without explaining how these actions are consistent with her authority under the statute."[75] The court said, "in the absence of such discussion the court can only conclude that the action was arbitrary and capricious."[76]

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[69] *Id.*

[70] 809 F.2d 847 (D.C. Cir.), *cert. denied*, 484 U.S. 819 (1987).

[71] *Id.* at 852.

[72] *Id.*

[73] *Id.*

[74] *Id.*

In *Action on Smoking & Health v. CAB*,[77] the District of Columbia Circuit vacated an agency rule rescinding certain earlier regulations that afforded protections to nonsmokers against breathing tobacco smoke, finding the CAB's explanation for the action "palpably inadequate."[78] The agency's refusal to promulgate several other regulations that had been suggested by members of the public was also set aside because the CAB failed to provide an adequate explanation for their rejection.[79]

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[75] *Id.* at 854.

[76] *Id.*

[77] 699 F.2d 1209 (D.C. Cir. 1983).

[78] *Id.* at 1217.

[79] *Id.* at 1217-19. The court, referring to the APA's requirement that the public have an opportunity to comment on proposed rules, and quoting *Alabama Power Co. v. Costle*, 636 F.2d 323, 384 (D.C. Cir. 1979), ruled that the opportunity to comment "is meaningless unless the agency responds to specific points raised by the public." 699 F.2d at 1217. Subsequently, the CAB reissued a part of the revised rule without notice and comment, accompanied by what the agency argued was an adequate statement of reasons. This second rule was also vacated. *Action on Smoking & Health v. CAB*, 713 F.2d 795 (D.C. Cir. 1983). Rejecting the argument that notice and comment was unnecessary because the earlier remand required the agency only to provide an adequate explanation for the rule, the court held that the statement of basis and purpose must be "contemporaneous" with the rule issued; the CAB statement, issued two years later, did not "accompany" the rule and consequently was treated by the court as a *post hoc* explanation of the rule. *Id.* at 799-801. Nor could the rule be upheld as a "new" rule, since the agency had not sought notice and comment, and the APA's "good cause" exemption to

Thus, an agency must invest a great deal of time and effort in preparing the statement of basis and purpose if its rule is to withstand close judicial review. An inadequate statement may result in the rules being remanded by the reviewing court, since an agency cannot rely on briefs to the court as the vehicle for explanation of the basis for a rule. Such later justifications are highly vulnerable as *post hoc* rationalizations that will be ignored by the court.

It is also critical that the agency deal fully with major alternative resolutions for the issues in the proceeding, explaining clearly why they were rejected in favor of the option selected. While obviously it would be difficult or impossible for the agency to discuss all possible alternatives, it must address significant matters.[80] The cases discussed above show that where the agency is rescinding or modifying a rule, it must fully explain its reasons for doing so and for not adopting alternative ways of changing the existing regulations. Of particular importance is the agency's explanation of how the regulation furthers the policies of its enabling statute.[81] Where the final

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the notice-and-comment requirements was inapplicable. *Id.* at 801.

See also Action for Children's Television v. FCC, 821 F.2d 741, 745 (D.C. Cir. 1987) (invalidating FCC's withdrawal of children's television commercialization guidelines because of inability to "unearth" a reasoned basis for the agency's action). *Accord: Lloyd Noland Hospital & Clinic v. Heckler* 762 F.2d 1561, 1566-67 (11th Cir. 1985).

[80] *See* discussion of the Supreme Court's *State Farm* decision, *supra*, text accompanying nn. 60-65.

[81] *See, e.g., Hazardous Waste Treatment Council v. EPA*, 886 F.2d 355, 365 (D.C. Cir.1989) (EPA statement of basis and purpose inadequate where it adopted a particular approach in its NPRM, and then in its final rule "proceed[ed] in a different direction simply on the basis of an unexplained and unelaborated statement that it might have been wrong when it

rule varies from the proposal, the preamble should explain in as much detail as possible why the final rule is a "logical outgrowth" of the proposal.[82]

Courts have consistently held that the agency need not respond to each individually identified comment in the statement of basis and purpose. It is enough that the agency discuss the significant issues raised in the comments.[83] Frequently, interested persons will make the same points, and responding to each comment would be unnecessarily repetitive. However, "boilerplate" statements that all comments were carefully considered, without further discussion, are not likely to receive a favorable reaction from reviewing courts.[84]

Additional requirements for agency response to comments may apply to some rulemakings. The Regulatory Flexibility Act requires the final regulatory flexibility analysis to evaluate public comments on the initial analysis and to state any changes made in the rule in response to the comments.[85] Agencies preparing final environmental impact statements must respond to comments received on the initial EIS.[86] As

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earlier concluded otherwise"); *International Union, UAW v. Pendergrass*, 878 F.2d 389, 399-400 (D.C. Cir. 1989).

[82] *See* Part III, Ch. 3(D).

[83] *See Northside Sanitary Landfill, Inc. v. Thomas*, 849 F.2d 1516 (D.C. Cir. 1988), *cert. denied*, 109 S. Ct. 1528 (1989).

[84] The Selective Service System's final rules governing alternatives to military service provide an illustration of this kind of statement. The preamble stated: "All comments that were received timely have been carefully considered. The final rule is identical with the proposed rule." 48 Fed. Reg. 16,675, 16,676 (1983). *See also Independent U.S. Tanker Owners Comm. v. Lewis*, 690 F.2d 908, 919 (D.C. Cir. 1982).

[85] 5 U.S.C § 604(a)(2).

[86] 40 C.F.R. § 1503.4.

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discussed earlier,[87] under the Paperwork Reduction Act, OMB has the right to comment on an information collection requirement in a proposed rule,[88] and the agency's response to OMB's comments must accompany Federal Register publication of its final rule.[89] Finally, Executive Order No. 12,291 requires an agency to respond to OMB's views in the "rulemaking file,"[90] and it is sensible to include this response in the statement of basis and purpose.

Although in many cases, a preamble may be very detailed,[91] the agency's statement of the basis and purpose will be tailored to each record and each agency action. Thus, rules promulgated by health and safety regulatory agencies are often accompanied by preambles having a section-by-section analysis explaining the rationale for adoption of rule provisions, and for rejecting alternatives.[92] Where the costs and technological aspects of a major regulation are particularly in issue, a more extensive summary of the regulatory impact analysis is normally included.[93]

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[87] *See* Part III, Ch. 2(B).

[88] 44 U.S.C. § 3504 (h)(2), (4) and (5).

[89] 44 U.S.C. § 3504(h)(3).

[90] Exec. Order No. 12,291, § 3(f)(2), *reprinted in* 5 U.S.C. § 601 note.

[91] An example of a very detailed statement of basis and purpose is the NHTSA preamble to the Final Rule on "Federal Motor Vehicle Safety Standard; Occupant Crash Protection," issued July 17, 1984. 49 Fed. Reg. 28,962 (1984). This rule was issued following the Supreme Court's remand in *State Farm*.

[92] *See, e.g.*, OSHA, Final Rule, Occupational Exposure to Formaldehyde, 52 Fed. Reg. 46,168 (1987), "Summary and Explanation of the Standard," *Id.* at 46,242-299.

[93] *See id.* at 46,237-42, "Summary of Regulation Impact and Regulatory Flexibility Analysis."

C. Publication of the Final Rule

The APA requires agencies to publish in the Federal Register all "substantive rules of general applicability."[94] Failure to publish makes a final rule unenforceable against any person not having actual and timely notice of its terms.[95] The APA requires that the statement of basis and purpose be incorporated in the rule,[96] so the statement of basis and purpose is also subject to the publication requirement. The Regulatory Flexibility Act gives the agency the option of either publishing the final regulatory flexibility analysis in the Federal Register or including instructions to the public on how to obtain copies of the analysis.[97] Executive Order No. 12,291 requires that final regulatory impact analyses be made available to the public, but does not mandate publication in the Federal Register.[98]

1. *Federal Register Requirements*

Title 1 of the Code of Federal Regulations contains the rules of the Administrative Committee of the Federal Register governing the filing and publication of documents in the Federal Register. An earlier chapter discussed the general format requirements that apply to documents submitted for publication in the Federal Register, as well as the requirements governing incorporation by reference of material into rules.[99]

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[94] 5 U.S.C. § 552(a)(1)(D).

[95] 5 U.S.C § 552(a)(1).

[96] 5 U.S.C. § 553(c).

[97] 5 U.S.C. § 604(b).

[98] Exec. Order No. 12,291, § 3(h), *reprinted in* 5 U.S.C. § 601 note.

[99] *Supra*, Part III, Ch. 3(C).

However, other requirements and provisions are particularly relevant to publication of *final* rules.

First, agencies should not expect the Office of the Federal Register to publish a final rule that does not comply with the Register's minimum requirements.[100] One requirement agencies should be aware of is that the Office of the Federal Register "will not accept a document for filing and publication if it combines material that must appear under more than one category in the *Federal Register*."[101] Thus, a single document containing both final rule text and proposed rule text will not be accepted for publication. The reasons for this requirement are that proposed and final rules appear in different sections of the Federal Register, and certain categories of documents, such as final rules, are included in the Code of Federal Regulations, while other categories appear only in the daily Federal Register.

Ordinarily, agencies may not cross-reference the rules of another agency.[102] From a practical point of view, use of cross-referencing to replace regulatory text makes the Federal Register system difficult to use, since the reader would have to look outside an agency's regulations to ascertain the nature of the entire regulatory scheme.

Agencies also must submit the full text of a final rule to the Office of the Federal Register for publication, unless the

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[100] The Director of the Federal Register is specifically authorized to return non-conforming documents to the issuing agency. 1 C.F.R. § 2.4(b).

[101] 1 C.F.R. § 18.2(a). The categories of Federal Register documents are listed in the Office of the Federal Register's Document Drafting Handbook (April 1986) at 5-7.

[102] 5 U.S.C. § 552(a) states that each agency must separately state and currently publish its regulations. *See also* 1 C.F.R. § 21.21.

Director of the Federal Register approves incorporation by reference of material in the rule. This requirement is statutory,[103] and failure to comply with it can lead to invalidation of the rule.[104] To avoid the expense of publication, some agencies have attempted to incorporate by reference agency-produced materials into final rules. However, the rules of the Federal Register generally do not allow agencies to incorporate by reference documents of the agency, or material previously published in the Federal Register or the United States Code.[105] An agency will have violated the Administrative Committee of the Federal Register's regulations if it publishes in the Federal Register a document that attempts to incorporate by reference the text of a proposed rule previously published in the Federal Register.[106]

The Administrative Committee of the Federal Register has published detailed rules on "Preparation and Transmittal of Documents Generally."[107] In particular, these rules prescribe a format for preambles to Federal Register documents[108] and require that they contain the following information:

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[103] Section 552(a)(1)(D) of the APA requires agencies to publish substantive rules of general applicability. Although agencies are not required to publish the text of a proposed rule (5 U.S.C. § 553(b)), final rules must be published in their entirety.

[104] *See, e.g., Appalachian Power Co. v. Train*, 566 F.2d 451, 455 (4th Cir. 1977).

[105] 1 C.F.R. § 51.7(b), (c).

[106] 1 C.F.R. §§ 21.1 and 21.21(c). When an agency incorporates in the text of the rule itself all applicable requirements, this serves the interest of promoting compliance. *See, e.g.*, OSHA, Final Rule, Electrical Standards for Construction, 51 Fed. Reg. 25,294, 25,296 (1986) (revising construction safety standard and incorporating relevant National Electrical Code (NEC) requirements into the text of the standard so that "employers will no longer have to refer to the NEC to determine their obligations under OSHA").

[107] 1 C.F.R. Part 18.

1. The name of the issuing agency.

2. Summary. This is a "brief statement", "in simple language", of the action taken, the reasons for the action, and its intended effect.

3. Relevant dates, such as effective date, hearing date, etc.

4. Relevant addresses.

5. Names and addresses of agency persons to contact for further information.

6. Supplementary Information. This is the main body of the preamble. The agency is required in this section to include a discussion of the background and major issues; in the case of a final rule, how the final rule is different from the proposal; "a response to substantive public comments received"; and any other appropriate information.

Agencies also must observe the Adminstrative Committee of the Federal Register's filing rules. The Federal Register Act requires all documents, including rules, to be "filed" with the Office of the Federal Register for publication, and "[u]pon filing, at least one copy shall be immediately available for public inspection in the Office."[109] But the Administrative Committee does not consider delivery of a document to the Register as "filing." Its regulations provide that:

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[108] 1 C.F.R. § 18.12. *See also* 1 C.F.R. Part 22 ("Preparation of Notices and Proposed Rules"); Document Drafting Handbook, *supra* n. 101, Ch. III.

[109] 44 U.S.C. § 1503.

> A document is considered filed with the Office of the Federal Register after it has been received and processed by the OFR and made available for public inspection . . . .[110]
>
> The OFR must file each document for public inspection on the working day before date of publication. The issuing agency may request in writing an earlier filing date.[111]
>
> . . .
>
> The OFR will not release information concerning a document to the public before the document is filed for public inspection.[112]

The Federal Register filing requirements are especially important to agencies issuing emergency rules under the APA or some other statute. If given advance warning, the staff of the Office of the Federal Register will work with agencies to expedite the filing and publication of emergency rules.[113]

Besides establishing publication requirements,[114] the Office of the Federal Register provides valuable assistance and services to agencies publishing final rules. For example, the Office of the Federal Register will publish rules as a separate part of the Register, and agencies can request overruns of the separate part.[115]

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[110] 1 C.F.R. § 1.1, 17.2

[111] 1 C.F.R. § 3.2(b), 17.2

[112] 1 C.F.R. § 17.1

[113] The Office of the Federal Register has special rules for publication and filing of emergency rules, 1 C.F.R. §§ 17.3-17.6, and the Document Drafting Handbook contains a special form for requesting special handling for documents, n. 101 *supra*, at 69.

[114] It should be noted that the Administrative Committee's format requirements are not intended to affect the validity of any document that is "filed and published under law." 1 C.F.R. § 5.1(c).

2. *"Issuance" and "Promulgation" of the Final Rule*

Under 28 U.S.C. § 2112, prior to its amendment in 1988, the precise date and time of issuance of a rule was critical for purposes of selection of venue for court review. Thus, under the original statute, review of the rule would take place in the circuit in which the proceeding "was first instituted." This gave rise to the much-criticized "race-to-the-courthouse" phenomenon, where each party sought to obtain review of the rule in a forum it thought favorable to its point of view. However, following a recommendation of the Administrative Conference,[116] Congress in 1988 amended 28 U.S.C. §2112 to provide for random selection of a court of appeals for review purposes from among all courts in which multiple petitions for review were filed within 10 days of the issuance of the order by the agency.[117] Thus, the "race for the courthouse" is eliminated for all practical purposes, since all petitions filed within ten days of the issuance of the order are treated equally for venue purposes and there is no incentive for a party to be the first to file.[118]

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[115] 1 C.F.R. § 12.1.

[116] Recommendation No. 80-5, "Eliminating or Simplifying the 'Race to the Courthouse' in Appeals from Agency Action," 1980 ACUS Recommendations & Reports 25.

[117] Pub. L. No. 100-236, 101 Stat. 1731 (1988), *codified at* 28 U.S.C. § 2112(a).

[118] *See also* discussion *infra*, Part IV, Ch. 1 (D). On the question of when a rule is "issued" or "promulgated" for purposes of determining the application of the ten-day rule, *see United Technologies Corp v. OSHA*, 836 F.2d 52 (2d Cir. 1987); *National Grain & Feed Ass'n v. OSHA*, 845 F.2d 345 (D.C. Cir. 1988).

FEDERAL AGENCY RULEMAKING

PART IV: JUDICIAL REVIEW OF AGENCY RULEMAKING

The three chapters in this Part offer a general summary of the law on judicial review of agency rulemaking action. Chapter 1 considers the availability of review, including such topics as reviewability, standing, timeliness and venue. Chapter 2 deals with the scope of judicial review, and discusses the relationships, and the differences, between the various standards of review applied by the courts when reviewing agency rules. Chapter 3 deals with an increasingly important area of the law: court review of agency inaction. In the rulemaking context, this includes suits where the agency has refused to initiate rulemaking, suits alleging that an agency has unreasonably delayed the completion of rulemaking, and suits where an agency refused to issue a rule after the rulemaking has been completed.

CHAPTER 1

AVAILABILITY OF JUDICIAL REVIEW

This chapter considers a variety of topics related to the availability of judicial review of agency action. Unlike most topics included in this Guide, which relate specifically to rulemaking, the topics in this chapter cut across much of the field of administrative law.

Reviewability -- whether the action in question is reviewable at all -- will be discussed first. Then the issue of who has standing to challenge a rule will be considered. Next is a discussion of the proper forum for review -- the court of appeals or the district court -- and the proper venue for the proceeding. Finally, several issues relating to timeliness of a petition for review will be discussed: whether the petitioner is required to exhaust administrative remedies before obtaining review, and whether the court deems the challenged agency action to be "final" and "ripe" for purposes of review; whether review may be obtained prior to enforcement against a violation of the rule; and whether review must be sought within the time prescribed by a statute.

A. Is the Agency Action Reviewable?

In *Citizens to Protect Overton Park v. Volpe,*[1] the Supreme Court addressed the threshold question whether petitioners were entitled to "any judicial review" of the Secretary of Transportation's action approving the building of a road through a park. The Supreme Court applied the presumption of reviewability that is embodied in section 701 of the APA. Section 701 provides that the action of "each authority of the Government of the United States" is subject to judicial review, except where "statutes preclude judicial review" [section 701(a)(1)] or "where agency action is committed to agency discretion by law" [section 701(a)(2)]. The Court found no indication in the applicable statute that Congress sought to limit judicial review and no "showing of 'clear and convincing' evidence of a . . . legislative intent to restrict access to judicial review," as required by the Supreme Court's earlier decision in *Abbott Laboratories v. Gardner.*[2] Further, the Supreme Court said, the exception from review for actions "committed to agency discretion" in the APA is narrow and is applicable only in "rare instances where 'statutes are drawn in such broad terms that in a given case there is no law to apply.'"[3] This, the Court held, was not the situation in *Overton Park.*

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[1] 401 U.S. 402 (1971).

This presumption of reviewability, articulated by the Supreme Court in the *Overton Park* and *Abbott Laboratories* decisions, has been consistently applied over the years by the courts except in the context of challenges to agency refusals to enforce a statute.[4] Moreover, enabling statutes for regulatory and benefit programs typically provide for court review of agency action; and where none is expressly provided, the APA has been the basis for court review except in the rare case where one of the APA exceptions is applicable.

The issue of reviewability usually reaches the courts when there is some indication that Congress may have intended to preclude judicial review. In two recent cases, the Supreme Court considered the reviewability of determinations by the

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[2] *Id.* at 410, citing *Abbott Laboratories v. Gardner*, 387 U.S. 136, 141 (1967). *Abbott Laboratories* raised the question of the availability of court review of a rule at the preenforcement stage, and is discussed *infra*, subs. (E).

[3] 401 U.S. at 410, quoting the legislative history of the APA, S. Rep. No. 752, 79th Cong. 1st Sess. 26 (1945).

[4] This exception, developed by the Supreme Court in *Heckler v. Chaney*, 470 U.S. 821 (1985), is discussed *infra*, Part IV, Ch. 3.

Secretaries of Agriculture and Health and Human Services. *Block v. Community Nutrition Institute*[5] involved the reviewability of milk market orders issued by the Secretary of Agriculture under the Agricultural Marketing Agreement Act of 1937. The Supreme Court held that the presumption favoring judicial review would be overcome when a contrary Congressional intent was "fairly discernible in the statutory scheme."[6] The Court said that *Abbott Laboratories'* "clear and convincing" test was not a "rigid evidentiary test but a useful reminder to courts that, where substantial doubt about congressional intent exists [on the review issue], the presumption favoring review of administrative action is controlling."[7] However, since it was "fairly discernible" from the legislative scheme that Congress did not intend to grant to consumers the right to review milk market orders, the Court would carry out that intent.[8]

The *Community Nutrition* decision seemed to have backed away somewhat from the strongly-stated presumption of review in *Abbott Laboratories* and *Overton Park*. Whatever the proper understanding of that decision, in 1986 the Supreme Court returned to a more literal application of the "clear and convincing" test. In *Bowen v. Michigan Academy of Family*

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[5] 467 U.S. 340 (1984).

[6] *Id.* at 351, quoting *Association of Data Processing Service Orgs., Inc. v. Camp*, 397 U.S. 150, 157 (1970).

[7] *Id.*

[8] *Id.* The Supreme Court acknowledged that milk handlers were afforded the right to review under the statute. *Id.* at 346. Looking at the entire "statutory scheme" the Court discovered a "clear" Congressional intent "to limit the classes" entited to participate in the development of milk market orders and to foreclose consumer participation in the regulatory process." *Id.* at 346-47.

Physicians,[9] involving review of HHS medicare regulations, the Supreme Court found that the presumption favoring judicial review had not been overcome, despite statutory language expressly limiting judicial review of certain types of issues. The Court stated: "We ordinarily presume that Congress intends the executive to obey its statutory commands" and therefore that the Congress "expects the courts to grant relief when an executive agency violates such command."[10]

In *Webster v. Doe*,[11] the Supreme Court held that a decision by the Director of the Central Intelligence Agency (CIA) to terminate an employee because of alleged homosexuality was not reviewable. The pertinent statute authorized the Director to terminate officers or employees of the agency "whenever he shall deem such termination necessary or advisable in the interests of the United States."[12] The Court construed section 701(a)(1) as precluding review where Congress expressed an intent to prohibit judicial review and section 701(a)(2) as precluding review in the rare instances where the statute is drawn in such broad terms that in a given case there is no law to apply.[13] Construing the CIA statute, the Court concluded that since the CIA Director may dismiss an employee whenever he or she "deems" it necessary, this standard "fairly exudes deference to the Director," and "forecloses the application of any meaningful judicial standard of review."[14]

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[9] 476 U.S. 667 (1986).
[10] *Id.* at 681.
[11] 486 U.S. 592 (1988).
[12] 50 U.S.C. § 403(c).
[13] 486 U.S. at 599.
[14] *Id.* at 600.

The *Webster* Court, however, held that *constitutional* claims against the Director were not barred, and stated that where Congress intends to preclude judicial review of constitutional claims, its intent to do so must be clear to avoid the "serious constitutional question" that would arise "if a federal statute were construed to deny any judicial forum for a colorable constitutional claim."[15]

B. Who Has Standing to Obtain Judicial Review

"Standing" refers to the question whether a person or entity challenging an agency action has the right to secure judicial review. The APA's standing section, 5 U.S.C. § 702, provides in pertinent part that:

> A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. . . . Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

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[15] *Id.* at 603, quoting *Bowen v. Michigan Academy of Physicans, supra* n. 9, 476 U.S. at 681 n. 12, where the Supreme Court noted that its disposition avoided the "serious constitutional claims" that would arise if it construed the statute to preclude constitutional claims under Part B of the Medicare program. Justices O'Connor and Scalia dissented in *Webster v. Doe* on the availability of review of constitutional issues.

Thus, section 702 states a presumption of judicial review of agency action if a challenge is brought by a person who is "adversely affected or aggrieved" by the action "within the meaning of a relevant statute."

Courts deciding the standing of a person challenging a rule also must heed limitations on federal court jurisdiction imposed by the "case or controversy" requirment of Article III of the Constitution.[16] Article III's "case or controversy" limitation has been interpreted to require that a party bringing an action in federal court demonstrate some actual or threatened injury.[17] In addition, parties seeking to establish constitutional standing also are required to show that their injury "fairly can be traced to the challenged action"[18] and that the injury is likely to be redressed by a favorable judicial decision.[19]

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[16] The Supreme Court explained Article III's "case-or-controversy" limitation in 1968 as follows:

> As is so often the situation in constitutional adjudication, those two words ["case" and "controversy"] have an iceberg quality, containing beneath their surface simplicity submerged complexities which go to the very heart of our constitutional form of government. Embodied in the words . . . are two complementary but somewhat different limitations. In part those words limit the business of federal courts to questions presented in an adversary context and in a form historically viewed as capable of resolution through the judicial process. And in part those words define the role assigned to the judiciary in a tripartite allocation of power to assure that the federal courts will not intrude into areas committed to the other branches of government. Justiciability is the term of art employed to give expression to this dual limitation placed upon federal courts by the case-and-controversy doctrine.

Flast v. Cohen, 392 U.S. 83, 94-95 (1968). The Court further remarked that "the emphasis in standing problems is on whether the party invoking federal court jurisdiction has 'a personal stake in the outcome of the controversy.'" *Id.* at 101 (citing *Baker v. Carr*, 369 U.S. 186, 204 (1962)).

A person challenging an agency rule who satisfies section 702's test is likely also to satisfy the injury requirement for constitutional standing. In fact, courts typically merge their discussion of section 702's "adversely affected or aggrieved" language with the constitutional injury requirement.[20]

Participants in agency rulemaking proceedings usually are members of a class that stands to benefit or lose by the final agency rule, and standing is not an obstacle to review. However, some rulemaking participants -- typically organizations[21] -- who have sought to challenge a rule have been denied standing because they failed to show that they would be adversely affected or injured by the rule.

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[17] *See Valley Forge Christian College v. Americans United for Separation of Church and State*, 454 U.S. 464, 473 (1982). The Supreme Court has held that injury to legal rights or interests and noneconomic interests, such as aesthetic and recreational interests or a stake in protecting First Amendment values, may be sufficient to confer standing. *Association of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150 (1970).

[18] *See Allen v. Wright*, 468 U.S. 737 (1984); *Valley Forge Christian College*, *supra* n. 17, 454 U.S. at 472 (citing *Gladstone, Realtors v. Village of Bellwood*, 441 U.S. 91, 99 (1979)).

[19] *Valley Forge Christian College*, *id.* (citing *Simon v. Eastern Kentucky Welfare Rights Org.*, 426 U.S. 26, 38, 41 (1976)). *See also Public Citizen v. FTC*, 869 F.2d 1541, 1547 (D.C. Cir. 1989).

[20] *See, e.g*, *Wilderness Society v. Griles*, 824 F.2d 4, 11 (D.C. Cir. 1987).

[21] The issue of the standing of organizations to challenge agency rules is discussed more fully *infra*, subs. (2).

In *Competitive Enterprise Institute v. Department of Transportation*,[22] the District of Columbia Circuit stated that "[p]etitioners do not have a right to seek court review of administrative proceedings merely because they participated in them."[23] In that case, an organization interested in regulatory matters challenged the Department of Transportation's regulations setting standards for computerized systems used by travel agencies to make airline reservations, alleging that the rule hindered its members' ability to make airline reservations and to obtain information needed to analyze airline regulations. The court held that while the organization had demonstrated an interest in receiving certain information, it had failed "to demonstrate that any airline or [computerized reservation system] would provide the information petitioners would like to receive."[24] The court concluded that the alleged injuries were "neither caused by the challenged regulation nor would be redressed by the relief they seek"[25] and, therefore, the petitioners did not satisfy the traceability or redressability elements of the standing test.[26]

In *Center for Auto Safety v. National Highway Traffic Safety Administration*,[27] the District of Columbia Circuit denied standing to a non-profit organization seeking to challenge

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[22] 856 F.2d 1563 (D.C. Cir. 1988).
[23] *Id.* at 1565.
[24] *Id.* at 1566.
[25] *Id.* at 1564.
[26] *Id.* at 1567.
[27] 793 F.2d 1322 (D.C. Cir. 1986).

NHTSA's fuel economy standards for passenger cars and light trucks. The Environmental Policy Institute (EPI) argued that its institutional interests would be adversely affected by NHTSA's decision to take into account consumer demand for less fuel-efficient vehicles, but it did not allege an injury to particular activities. The court held that EPI failed to establish the injury-in-fact necessary to establish standing,[28] and "although EPI participated in the rulemaking at the agency level and filed a motion for reconsideration by NHTSA, that participation does not, in and of itself, satisfy *judicial* standing requirements."[29]

In addition to the Constitution's "case or controversy" requirement, federal courts apply certain "prudential principles" to decide whether to grant standing to parties challenging agency action. These prudential standing principles are designed to avoid having courts decide abstract questions of wide public significance that other governmental institutions may be more competent to address.[30] Thus, courts may decline to accept jurisdiction where the plaintiff, rather than asserting his own legal rights and interests, rests his claim on the rights or interests of third parties.[31] Courts will refrain from deciding "'abstract questions of wide public significance' which amount to 'generalized grievances,' pervasively shared and most appropriately addressed in the representative branches."[32]

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[28] *Id.* at 1329 n. 41.

[29] *Id.* (emphasis in original). Although the court dropped EPI from the case, several other petitioners were found to have standing, thus preserving the lawsuit.

A different standing result was reached in *City of Los Angeles v. NHTSA*, 912 F.2d 478 (D.C. Cir. 1990). There a split panel of the District of Columbia Circuit held that environmental and consumer groups had standing to challenge fuel economy standards promulgated by NHTSA. The central issue was NHTSA's failure to prepare an environmental impact statement, and the court found the existence and purposes of the National Environmental Policy Act to be crucial to its standing decision. Judge Wald stated that "[g]iven the broad congressional mandate of NEPA, it can hardly be argued that [petitioner's] concerns about global warming do not fall within the zone of interest of NEPA. . . . . Thus [the petitioner], suing on behalf of its members, is 'aggrieved' within the meaning of NEPA and falls within its zone of interest, thereby satisfying the injury-in-fact requirement of standing." *Id.* at 495. Judge D. Ginsburg dissented, finding that petitioners "failed to explain how that injury [global warming] can be traced causally to the challenged decision and how the relief it seeks could redress the harm it foresees." *Id.* at 483. For a further discussion of "zone of interests," see subs. (1), *infra*.

Unlike Article III "case or controversy" requirements, Congress may by statute eliminate recourse to prudential standing principles by expanding standing to the full limit allowed by the Constitution.[33]

1. *The "Zone of Interests" Test*

The "zone of interests" test, first enunciated by the Supreme Court in 1970, is often included among the prudential standing principles, but it may also be viewed as an interpretation of 5 U.S.C. § 702. Because agency rules are based on statutes and review typically is under section 702, the zone of interests test is particularly important in the rulemaking context.

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[30] *Warth v. Seldin*, 422 U.S. 490, 499 (1974).

[31] *Valley Forge Christian College v. Americans United for Separation of Church and State*, *supra* n. 17, 454 U.S. at 474 n. 10 and accompanying text.

[32] *Id.* at 475 (citing *Warth v. Seldin*, 422 U.S. at 499-500). *See also Allen v. Wright*, 468 U.S. 737, 754-755 (1984); *International Primate Protection League v. Administrators of the Tulane Educational Fund*, 895 F.2d 1056, 1060 (5th Cir. 1990).

[33] *Center for Auto Safety v. NHTSA*, 793 F.2d at 1335 (citing *Warth v. Seldin*, 422 U.S. at 501). The D.C. Circuit concluded that "[t]he broad standing to challenge [fuel economy] standards established by [the statute] removes any necessity to limit judicial review for prudential reasons." *Id.* at 1336.

The test originated with *Association of Data Processing Service Organizations, Inc. v. Camp,*[34] in which Justice Douglas, writing the majority opinion, first addressed the injury requirement for constitutional standing, and then added: "apart from the 'case' or 'controversy' test", standing concerns the question whether the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question."[35] The Court went on to hold that the plaintiffs, who were in the business of supplying data processing services, had standing to challenge a Comptroller of the Currency ruling allowing national banks to provide data processing services to other banks and their customers.[36] The Court held that data processors were within the zone of interests established by the Bank Service Corporation Act.[37]

The dissenting justices in *Association of Data Processing Service Organizations* criticized the zone of interests test as a "wholly unnecessary and inappropriate second step upon the constitutional requirement for standing."[38] The test subsequently generated much confusion among the lower courts as well as criticism in legal literature.[39]

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[34] 397 U.S. 150 (1970).

[35] *Id.* at 153.

[36] The Court concluded: "The [Bank Service Corporation Act and the National Bank Act] are clearly 'relevant' statutes within the meaning of § 702. The Acts do not in their terms protect a specified group. But their general policy is apparent; and those whose interests are directly affected by a broad or narrow interpretation of the Acts are easily identifiable. It is clear that petitioners, as competitors of national banks which are engaging in data processing services, are within that class of 'aggrieved' persons who, under § 702, are entitled to judicial review of 'agency action.'" *Id.* at 157.

[37] *Id.* at 155.

Finally, in *Clarke v. Securities Industry Association*,[40] the Supreme Court attempted to clarify the test. *Clarke* also involved a challenge to a Comptroller of the Currency decision brought by competitors of national banks. The Comptroller had approved the applications of two national banks to establish offices offering discount brokerage services at various locations, and the respondent on appeal, an association of securities brokers and investment bankers, sought review on the ground that this action violated the National Bank Act's branching restrictions. The Court reviewed the legislative history of the McFadden Act (which had amended the National Bank Act) and concluded that the Securities Industry Association asserted "a plausible relationship to the policies underlying §§ 36 and 81 of the National Bank Act," and, therefore, had standing to bring the lawsuit.[41]

In deciding the standing question, the *Clarke* majority expounded at length on the meaning of the "zone of interests test" and sought to explain it as "a gloss on the meaning of [5 U.S.C. § 702],"[42] intended to place some limit on the broad

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[38] *Id.* at 169.

[39] Writing in 1982, Professor Davis wrote that "the 'zone' test is sometimes used, but most of the time it is not, and no guides exist as to whether or when it is used." 4 K. Davis, Administrative Law Treatise (2d. ed.) §24:17 at 273. *See also* sources cited in *Clarke v. Securities Industry Ass'n*, 479 U.S. 388, 396 n. 11 (1987).

[40] 479 U.S. 388 (1987).

[41] *Id.* at 403.

[42] *Id.* at 395, 440 n., 16.

"adversely affected" language of that provision.[43] The Court explained the test as follows:

> The "zone of interest" test is a guide for deciding whether, in view of Congress' evident intent to make agency action presumptively reviewable, a particular plaintiff should be heard to complain of a particular agency decision. In cases where the plaintiff is not itself the subject of the contested regulatory action, the test denies a right of review if the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit. The test is not meant to be especially demanding; in particular, there need be no indication of congressional purpose to benefit the would-be plaintiff.[44]

The Court emphasized that even though the interests represented in a petition challenging government action may fall within the "zone of interests" of a statute, a court also must determine if Congress, nevertheless, intended to preclude review for particular classes of plaintiffs.[45] To illustrate, the Court referred to its earlier decision, *Block v. Community Nutrition Institute*,[46] wherein it held that while milk handlers could obtain judicial review of milk pricing orders issued by the Secretary of Agriculture, the statutory scheme at issue did not contemplate that consumers would have that right.[47]

A post-*Clarke* case illustrating application of the zone of interests test to decide standing in a rulemaking case is

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[43] *Id.* at 397.
[44] *Id.* at 399-400 (footnote and citation omitted).
[45] *Id.*
[46] 467 U.S. 340 (1984).
[47] 479 U.S. at 399.

Hazardous Waste Treatment Council v. EPA.[48] The District of Columbia Circuit was petitioned by a trade association of firms engaged in the treatment of hazardous waste and the manufacture of waste treatment equipment to review an EPA rule under the Resource Conservation and Recovery Act of 1976. The gist of the complaint was that the EPA rule was not as comprehensive or as strict as the statute required, thus causing injury to the environment and a diminished market for their services and equipment.

The court concluded that association members whose waste treatment facilities would be adversely affected by contaminated waste clearly had standing to challenge the rule.[49] However, the court held that association members who complained of business injury did not have standing under the zone of interests test because their interest was only "marginally related" to the Act's environmental purposes.[50] The court said, "When we grant standing to a party with only an oblique relation to the statutory goal, we run the risk that the outcome could, even assuming technical fidelity to law, in fact thwart the congressional goal."[51] The association, therefore, was found to have standing to challenge only those aspects of EPA's rules that affected user or "consumer" interests, and not those aspects that related to business or competitor interests.[52]

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[48] 861 F.2d 277 (D.C. Cir. 1988), *cert. denied*, 109 S. Ct. 3157 (1989). *See also Public Citizen v. FTC, supra* n. 19, 869 F.2d at 1547 n. 8 (zone of interests test only "requires some indicia -- however slight -- that the litigant before the court was intended to be protected, benefited or regulated by the statute under which suit is brought" [citations omitted]).

[49] 861 F.2d at 282.

[50] *Id.* at 283. In earlier cases applying the zone of interests test, courts found that entrepreneurs seeking to protect competitive advantage had no standing to challenge OSHA standards which were issued under a statute whose purpose was worker safety, not business advantage. *See Fire Equipment Mfrs. Ass'n, Inc. v. Marshall*, 679 F.2d 679, 682 (7th Cir. 1982), *cert. denied*, 459 U.S. 1105 (1983); *Calumet Industries v. Brock*, 807 F.2d 225 (D.C. Cir. 1986).

2. *Organizational Standing and Injury Allegations*

As mentioned earlier, the standing of organizations to challenge agency action is particularly important with regard to review of agency rules. The principal guidance on the standing of an organization to challenge action affecting its members was provided by Supreme Court in 1977 in *Hunt v. Washington State Apple Advertising Commission.*[53] The Court there held that an association has standing to bring a suit on behalf of its members if the members would otherwise have standing to sue in their own right; the interests the association seeks to protect are germane to the association's purpose; and the litigation does not require the participation of individual members.[54]

This organizational standing test must be considered together with cases addressing the requirement that organizations allege injury to their specific activities or to their members' activities. The case law on this injury showing has been evolving.

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[51] 861 F.2d at 283-84.

[52] *Id.* at 285-87.

[53] 432 U.S. 333 (1977).

[54] *Id.* at 343. It is noteworthy that the Apple Advertising Commission was found to have standing even though it was not technically a membership organization. The Court reaffirmed these organizational standing requirements in *International Union UAW v. Brock*, 477 U.S. 274, 288-290 (1986); *see also Public Citizen v. FTC*, *supra* n. 19, 869 F.2d at 1545, 1551; *Center for Auto Safety v. NHTSA*, *supra* n. 27, 793 F.2d at 1328-29.

In *Sierra Club v. Morton*,[55] the Supreme Court affirmed that standing may be obtained by those seeking to redress injury to aesthetic and environmental interests, even though their injury is shared by a large number of people. However, the Court held that not only must there be an injury to a cognizable interest, but the standing test also requires that "the party seeking review be himself among the injured."[56] Because the Sierra Club had not alleged injury to any individual members of the organization, but only its own longstanding commitment to protecting the environment, the Court denied standing.[57]

Sierra Club was followed by a case that may be the "high-water mark" of liberal standing. In *United States v. Students Challenging Regulatory Agency Procedures (SCRAP)*,[58] an association of five law students was found to have standing to challenge a general surcharge on freight shipped by rail on the ground that the rate increase would discourage the use of recyclable materials. SCRAP alleged that each of its members was caused to pay more for finished products, that each of its members [uses the Washington, D. C. area for recreation and aesthetic purposes] and that these uses have been adversely affected by the increased freight rates, that each of its members breathes the air within the Washington metropolitan area . . . and that this air has suffered increased pollution caused by the modified rate structure, and that each member has been forced to pay increased taxes because of the sums which must be expended to dispose of otherwise reusable waste materials."[59] The Court granted standing on the basis of these allegations, stating: "To deny standing to persons who are in fact injured simply because many others are also injured, would mean that the most injurious and widespread Government actions could be questioned by nobody. We cannot accept that conclusion."[60]

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[55] 405 U. S. 727, 734 (1972).

[56] *Id.* at 734-35.

[57] *Id.* at 739-40. For a recent application of the individual injury requirement to deny standing, *see International Primate Protection League v. Administrators of the Tulane Educational Fund*, 895 F.2d 1056 (5th Cir. 1990).

[58] 412 U.S. 669 (1973).

In 1990 the Supreme Court returned to the question of organizational injury allegations in petitions for review in *Lujan v. National Wildlife Federation*,[61] in which the Court denied the National Wildlife Federation standing to obtain review of the Bureau of Land Management's administration of the Federal Land Policy and Management Act of 1976. The Federation alleged that the Bureau had failed to properly fulfill numerous duties under various authorities, with the result that previously withdrawn lands would be returned to the public domain and opened up to mining activities that would destroy the lands' natural beauty, thus interfering with the Federation's aesthetic and environmental interests. Unlike the situation in *Sierra Club v. Morton*,[62] the Federation had submitted affidavits by individual members who alleged their interests would be injured by a continuation of the Bureau's actions.[63] The government nevertheless sought dismissal of the case for lack of standing.

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[59] *Id.* at 678.
[60] *Id.* at 688.
[61] 110 S. Ct. 3177 (1990).
[62] *Supra* n. 55.

Justice Scalia, writing for the Court, found that the Federation was a proper representative of the individual members' interests[64] and that the interests raised were within the zone of interests of the statute.[65] The Court nevertheless held that the Federation lacked standing under 5 U.S.C. § 702 to bring the action in federal court, concluding that the facts alleged in the affidavits of individual organization members did not establish that those particular members' interests would be affected by the government actions complained of.[66]

Although dicta in the decision was critical of the *SCRAP* case,[67] the long-term significance of the *Lujan* case is unclear because of procedural differences that distinguish it from *SCRAP* and other standing cases.[68]

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[63] 110 S. Ct. at 3184.

[64] The Court found that the allegedly affected interests set forth in the individuals' affidavits were sufficiently related to the purposes of the organization, so that "respondent [National Wildlife Federation] meets the requirements of § 702 if any of its members do." *Id.* at 3187 (citing *Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333 (1977)).

[65] *Id.* ("We also think that whatever 'adverse effect' or 'aggrievement' is established by the affidavits was 'within the meaning of the relevant statute' -- *i.e.*, met the 'zone of interests' test.")

[66] *Id.* at 3189.

[67] Justice Scalia characterized the *SCRAP* case as an "expansive expression of what would suffice for § 702 review" which "has never since been emulated by this Court." *Id.* at 3189.

[68] In *SCRAP* the Court responded to railroads' contention that SCRAP could never prove that a rate increase would have the environmental and other effects alleged in the petition for review by stating: "[W]e deal here simply with the pleadings in which the appellees alleged a specific and perceptible harm that distinguished them from other citizens who had not used the natural resources that were claimed to be affected. If, as

C. The Proper Forum for Review: Court of Appeals or District Court

The forum for judicial review of agency rules, as for other agency action, is determined by statute. It may be governed by a particular statute, such as the one authorizing the rule, or the statute governing the review of orders of particular agencies. If not, review would be predicated on the more general jurisdictional statutes, and would be sought in the district court. This latter is normally called, somewhat misleadingly, "nonstatutory review."

1. Statutory Review

Statutes containing judicial review provisions applicable to rulemaking generally call for direct, preenforcement review in the courts of appeals. Most of the major rulemaking programs are covered by such a provision, and statutes establishing the

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the railroads now assert, these allegations were in fact untrue, then the appellants should have moved for summary judgment on the standing issue and demonstrated to the District Court that the allegations were sham and raised no genuine issue of fact." 412 U.S. at 689 (footnotes omitted).

By contrast, the standing issue in *Lujan* was before the Court on a motion by the government for summary judgment. Under Rule 56(e) of the Federal Rules of Civil Procedure, the party opposing a motion for summary judgment must set forth "specific facts showing that there is a genuine issue for trial." Regarding the specificity required by Rule 56(e), Justice Scalia stated: [W]here the fact in question is the one put in issue by the § 702 challenge here -- whether one of respondent's members has been, or is threatened to be, 'adversely affected or aggrieved' by Government action -- Rule 56(e) is assuredly not satisfied by averments which state only that one of respondent's members uses unspecified portions of an immense tract of territory, on some portions of which mining activity has occurred or probably will occur by virtue of the government action." 110 S. Ct. at 3189.

Lujan was decided on ripeness as well as standing grounds. *See* 110 S. Ct. at 3189-91, discussed *infra*, subs. (E)(2)(a).

programs normally contain requirements as to venue, timing of review, and scope of review.[69]

One special judicial review statute, the Administrative Orders Review Act (colloquially known as the Hobbs Act),[70] governs the review of "orders" of several important agencies.[71] Court decisions have established that such "orders" issued by these agencies include "rules" for the purpose of judicial review.[72] The Act provides for review in the courts of appeals.[73]

The Administrative Conference has recommended placing direct review of rules in the court of appeals in instances where (1) the rule is so significant that a district court decision would likely be appealed, and (2) where other "orders" of agencies are already reviewed that way. The complete Conference statement on the subject is as follows:

> The appropriate forum for the review of rules promulgated pursuant to the notice-and-comment procedures of 5 U.S.C. 553 should be determined in the light of the following considerations:
>
> (a) Absence of a formal administrative record based on a trial-type hearing does not preclude direct review of rules by courts of appeals because: (i) Compliance with procedural

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[69] Many of these are discussed *infra*.

[70] 28 U.S.C. §§ 2341-51.

[71] The Act applies, for example, to certain orders of the Federal Communications Commission, Department of Agriculture, Federal Maritime Commission, Nuclear Regulatory Commission, Interstate Commerce Commission, and Merit Systems Protection Board.

[72] *See* Currie & Goodman, *Judicial Review of Federal Administrative Action: Quest for the Optimum Forum*, 75 Colum. L. Rev. 1, 39-40 (1975).

[73] 28 U.S.C. § 2342.

> requirements of 5 U.S.C. 553, including the requirement of a statement of reasons for the rule, will ordinarily produce a record adequate to the purpose of judicial review, and (ii) the administrative record can usually be supplemented, if necessary, by means other than an evidentiary trial in a district court.
>
> (b) Direct review by a court of appeals is appropriate whenever: (i) An initial district court decision respecting the validity of a rule will ordinarily be appealed or (ii) the public interest requires prompt, authoritative determination of the validity of the rule.
>
> (c) Rules issued by agencies that regularly engage in formal adjudication and whose "orders" are subject by statute to direct review by the courts of appeals will normally satisfy the criteria of (b) above and in any event should be reviewable directly by the court of appeals.
>
> (d) Rules of other agencies that do not satisfy the criteria of (b) above should generally be reviewable in the first instance by the district courts.[74]

In October 1984, the District of Columbia Circuit, in *Telecommunications Research and Action Center v. FCC* (*TRAC*),[75] decided that where a statute places review of agency action in the court of appeals, a suit seeking relief that might affect the court of appeals' *future* jurisdiction is also subject to the exclusive jurisdiction of the court of appeals. *TRAC* involved a suit by public interest groups and non-profit corporations for a writ of mandamus to compel the FCC to decide certain unresolved proceedings that had been pending for some time. Recognizing that the law of the circuit was in "disarray" on the issue of the proper forum for claims of agency unreasonable delay, the court attempted to resolve the jurisdictional question.[76] The court first noted that there was no dispute that the court of appeals, which was assigned jurisdiction by statute over final FCC actions, also had jurisdiction over claims of unreasonable delay.[77] It then reached the further conclusion, based on an analysis of the relevant statutes and "compelling policy reasons," that the court of appeals' jurisdiction was exclusive.[78] Noting that appellate courts "develop an expertise concerning the agencies assigned them for review," the court concluded that exclusive court of appeals jurisdiction "promotes judicial economy and fairness to the litigants by taking advantage of that expertise" and "eliminates duplicative and potentially conflicting review and the delay and expense incidental thereto."[79]

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[74] Recommendation No. 75-3, "The Choice of Forum for Judicial Review of Administrative Action," ¶ 5, 1 C.F.R. § 305.75-3.

[75] 750 F.2d 70 (D.C. Cir. 1984).

The language of the *TRAC* decision is broad, and its holding has been applied to agencies other than the FCC and to rulemaking proceedings as well as to adjudication. Thus, for example, in *International Union, U.A.W. v. Donovan*,[80] the

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[76] *Id.* at 75. The court also considered the merits of the question when agency delay was "unreasonable". *Id.* at 79-81. See discussion *infra*, Part IV, Ch. 3(B)(2).

[77] This conclusion was based on the All Writs Act, 28 U.S.C. § 1651(a), the APA, § 5 U.S.C. §§ 555(b), 706(1), and statutes referring expressly to FCC orders, 28 U.S.C. § 2342(1) and 47 U.S.C. § 402(a).

[78] 750 F.2d at 78.

[79] *Id.* The court indicated, however, that there might be a "small category of cases," not subject to court of appeals review in which denial of review in the district court "will truly foreclose all judicial review."

[80] 756 F.2d 162 (D.C. Cir. 1985).

District of Columbia Circuit, noting that the OSHA statute vested exclusive review of OSHA standards in the court of appeals,[81] held that the court of appeals had exclusive jurisdiction in the case,[82] and that the district court properly transferred the case to the court of appeals.[83]

The Administrative Conference has recommended that as a general rule, the *TRAC* principles should be followed.[84] It also recommended that where jurisdiction of delay cases lies in the court of appeals, procedures be developed to ensure prompt and efficient disposition of the claims.[85]

2. *Nonstatutory Review*

If there is no specifically applicable judicial review provision governing the agency's rule, the challenger will normally attempt to seek review through an action for an injunction or declaratory relief in the district court. Jurisdiction must be obtained through one of the general jurisdictional statutes. The one most frequently asserted is 28 U.S.C. §1331, the so-called "federal question" provision, which gives the district courts "original jurisdiction of all civil actions wherein the matter in controversy . . . arises under the Constitution, laws, or treaties of the United States . . . ." Until 1976, this section also contained a $10,000 jurisdictional amount requirement, but following the recommendation of the Administrative Conference,[86] this provision was eliminated for suits against the United States, a federal agency, or federal officer or employee acting in his or her official capacity.[87] Other jurisdictional bases are less often invoked since this 1976 amendment, but possibilities include 28 U.S.C. §1337 (actions arising under commerce-related statutes), and 28 U.S.C. §1361 (mandamus jurisdiction). The APA was held not to be an independent basis for jurisdiction in 1977, but only after the question was rendered largely moot by the amendment to section 1331.[88]

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[81] 29 U.S.C. § 655(f).

[82] 756 F.2d at 165. The case involved a suit to force OSHA to issue a formaldehyde standard.

[83] *Id.*

[84] Recommendation No. 88-6, "Judicial Review of Preliminary Challenges to Agency Action," 1 C.F.R. § 305.88-6. The Recommendation is based on Sargentich, *Juridictional Debate in Administrative Law: A Comment on Telecommunications Research and Action Center v. FCC*, 1988 ACUS Recommendations & Reports 281. An article based on this study appears in Sargentich, *The Jurisdiction of Federal Courts in Administrative Cases: Developments*, 41 Admin. L. Rev. 201 (1989).

[85] Recommendation No. 88-6, *supra* n. 84, ¶3. The District of Columbia Circuit amended its local rules in conformance with the ACUS Recommendation, to provide that petitions alleging a claim of unreasonable delay of administrative agency action be treated as motions and processed expeditiously. Rule 7(j), Local Rules of the Court of Appeals for the District of Columbia Circuit.

Nonstatutory review is conducted by a district court, but such review is on the administrative record and is normally subject to the "arbitrary and capricious" review provisions. District courts usually rely on the rulemaking record assembled by the agency, and if that record is inadequate, a remand to the agency is the remedy.[89]

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[86] Recommendation No. 68-7, "Elimination of Jurisdictional Amount Requirement in Judicial Review," I ACUS Recommendations & Reports 170.

[87] Pub. L. No. 94-574, 90 Stat. 2721, *codified at* 28 U.S.C. § 1331. In 1980, Congress eliminated the jurisdictional amount for all federal question cases. Pub. L. No. 96-486.

[88] *Califano v. Sanders*, 430 U.S. 99 (1977).

[89] *Camp v. Pitts*, 411 U.S. 138, 142-43 (1973). *Cf. National Nutritional Foods v. Weinberger*, 512 F.2d 688 (2d Cir.), *cert. denied*, 423 U.S. 827 (1975). District courts sometimes do

D. The Venue (Location) of Review

There is no single provision governing venue for petitions for review of rules in the courts of appeals. The Administrative Orders Review Act, for example, provides for the filing of petitions in the circuit where "the petitioner resides or has its principal office, or in the [District of Columbia Circuit]."[90] Certain other specific statutes providing for review in the courts of appeals, such as the OSHA Act, contain similar venue language.[91] Other statutes provide for *exclusive* review of certain types of rules in the District of Columbia Circuit. The Clean Air Act, for example, provides for exclusive review of certain "nationally applicable" regulations in the District of Columbia Circuit, with "locally or regionally applicable" rules reviewable in "the appropriate circuit."[92] The Federal Water Pollution Control Act, on the other hand, places review of all rules under the Act in the circuit where the objecting party "resides or transacts such business."[93]

Critics of provisions permitting or requiring review in the District of Columbia Circuit have proposed changes in the venue laws in an attempt to have more cases filed in the "local" districts and circuits.[94] The Administrative Conference has

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hold evidentiary hearings on review of agency action, as where *de novo* review is required by statute, *e.g.*, 8 U.S.C. § 1105(a)(5) (review of deportation cases).

[90] 28 U.S.C. § 2343.

[91] 29 U.S.C. § 655(f).

[92] 42 U.S.C. § 7607(b)(i).

[93] 33 U.S.C. § 1369(b)(i). *See* ACUS Recommendation 76-4, "Judicial Review Under the Clear Air Act and Federal Water Pollution Control Act," 4 ACUS Recommendations & Reports 54; Currie, *Judicial Review Under Federal Pollution Laws*, 62 Iowa L. Rev. 1221 (1977).

[94] *See, e.g.*, National Legal Center for the Public Interest, Venue at the Crossroads (1982).

recommended *against* any fundamental changes in the venue laws governing suits against the government, although it did urge enactment of a provision that would require notification of state attorneys general of certain suits filed in the District Court for the District of Columbia and a modification of the venue transfer provision, 28 U.S.C. §1404, to explicitly providing that intervenors may seek transfer.[95]

Because the venue provisions in many of the individual statutes governing direct review of rules in the courts of appeals allow for review in several possible circuits, and because there are perceived differences in the various circuits' approach to judicial review, "forum shopping" opportunities abound. Consequently, multiple appeals are filed in different circuits, as parties seek to bring lawsuits in the forum thought to be most favorable to them. Prior to 1988, under 28 U.S.C. §2112(a), the agency was required to file the record of the proceedings in the circuit in which the *first* petition was filed. Since filing rules in the circuits normally permit cursory petitions for review, the "first to file" rule of section 2112(a) and modern communications technology combined to precipitate "races to the courthouse", which have been subject to bitter litigation[96] and widespread criticism.[97]

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[95] Recommendation No. 82-3, "Federal Venue Provisions Applicable to Suits Against the Government," 1982 ACUS Recommendations & Reports, vol. 1, at 15.

[96] *See, e.g., Industrial Union Dep't v. Bingham*, 570 F.2d 965 (D.C. Cir. 1977) (OSHA emergency standard for benzene), *discussed in* B. Mintz, OSHA: History, Law and Policy 207-14 (1984).

[97] *See, e.g.*, McGarity, *Multi-Party Forum Shopping for Appellate Review of Administrative Action*, 129 U. Pa. L. Rev. 302 (1980).

To reduce forum shopping litigation, the Administrative Conference in 1980 recommended legislation to authorize the Administrative Office of the U.S. Courts to oversee a random selection procedure for choosing the court with initial jurisdiction to conduct the review proceeding when multiple petitions have been filed.[98] This approach, designed to eliminate races to the courthouse by eliminating any advantage for "first filed" petitions, was adopted by Congress in January 1988.[99] Under this amendment to section 2112(a), if within 10 days of the issuance of the agency order, the agency receives petitions for review in two or more courts of appeals, the agency notifies the Judicial Panel on Multidistrict Litigation. The panel then designates "by means of random selection" a single court of appeals from among those in which petitions were filed and consolidates the petitions for review in that court of appeals. If only one petition for review is filed within the 10-day period, that court of appeals hears the appeal. The amendment provides that a stay may be issued by any court of appeals in which proceedings related to an agency order have been filed, but that the stay may be modified or revoked by any court of appeals to which the proceeding is transferred. Finally, the amendment, like the original section 2112, contains a provision: "For the convenience of the parties in the interest of justice, the court in which the record is filed may thereafter transfer all the proceedings with respect to that order to any other court of appeals."[100]

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[98] Recommendation No. 80-5, "Eliminating or Simplifying the 'Race to the Courthouse' in Appeals from Agency Action," 1980 ACUS Recommendations & Reports 25.

[99] Pub. L. No. 100-236, 101 Stat. 1731.

[100] 28 U.S.C. §2112(a)(3).

In July 1988, the Judicial Panel on Multidistrict Litigation issued implementing rules, which contain more detailed procedures for carrying out the amendment.[101] The selection process operates by having the clerk of the panel or its representative "randomly select a circuit court of appeals from a drum containing an entry for each circuit wherein a constituent petition is pending."[102] The rules expressly provide that multiple petitions in a single circuit "shall be allotted only a single entry in the drum."[103]

Absent some special statutory requirement, the venue of review of actions against the federal government is brought in district court and is governed by 28 U.S.C. § 1391(e), which allows suit "in any judicial district in which (1) a defendant in the action resides; or (2) the cause of action arose; or (3) any real property involved in the action is situated; or (4) the plaintiff resides if no real property is involved in the action." This obviously gives the plaintiff a wide latitude in choosing the forum.

E. The Appropriate Timing for Judicial Review

1. *Finality, Exhaustion and Ripeness*

The courts have developed a number of concepts to determine whether a case should be judicially reviewable at a particular time. These concepts, which include the notions of finality, exhaustion of remedies, and ripeness, are attempts to balance the efficient use of judicial and agency resources and interests of parties challenging agency action. The concepts, which will be discussed briefly here, are difficult to distinguish, and they overlap and interrelate in a number of ways.[104]

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[101] R. Pro. Jud. Panel on Multidistrict Litigation

[102] *Id.*, Rule 24.

[103] *Id.* This provision would negate any advantage derived from "stuffing the ballot box."

The "finality" requirement derives from the APA, which provides for judicial review of "final agency action."[105] This requirement is primarily concerned with protecting the integrity of the administrative process, and prevents waste of judicial resources considering an agency position which may be changed.[106] In the context of challenges to rulemaking, finality is generally not a major issue, if the rule being challenged is a final rule. As discussed below, however, if an agency's failure to act in a rulemaking context is being challenged, there may be a question whether the "action"; *i.e.*, the failure to act, is a final agency position.[107]

Exhaustion of administrative remedies is a prudential judicial construct that generally requires a party to go through all the stages of an administrative proceeding before going to court. This requirement ensures that the agency action being challenged is the final agency position, and that the agency has had the opportunity to bring its expertise to bear and to correct any errors it may have made at an earlier stage, thus potentially resolving disputes before they get to court.[108] Again, this issue, while important in many areas of administrative law, is not often an issue in judicial review of rules, since rulemaking procedures are generally complete before there is a rule to challenge.[109]

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[104] *See Ticor Title Ins. Co. v. FTC*, 814 F.2d 731 (D.C. Cir. 1987)(facial constitutional challenge to FTC's prosecutorial authority, where the court dismissed the claim, but split three ways on whether the dismissal was properly based on exhaustion, ripeness, or finality).

[105] 5 U.S.C. § 704.

[106] *See generally FTC v. Standard Oil Co. of California*, 449 U.S. 232 (1980).

[107] *See* subs. (E)(3) and Part IV, Ch. 3, *infra*.

The concept of "ripeness" is the one most likely to surface in a challenge to a rulemaking. Ripeness addresses the appropriateness of judicial review at a particular time, and is primarily concerned with ensuring that issues are in a posture fit for judicial review. As the Supreme Court said in *Abbott Laboratories v. Gardner*,[110] ripeness's "basic rationale is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties."[111]

Ripeness is a two-pronged concept: the issues must be "fit[] . . . for judicial decision" and delaying review must cause hardship for the challenging party.[112] Fitness for judicial decision depends on whether the issues are "legal" ones and whether the court or the agency would benefit from deferring review until the "agency's policies have crystallized" or the issues have been further refined.[113] The challenger's hardship, which must outweigh any interests in deferring review, must be more than speculative, and involve more than just money.[114]

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[108] *See generally McGee v. United States*, 402 U.S. 479 (1971).

[109] There may be situations in the context of challenges to agency delay or inaction where the failure to file a petition for rulemaking may prevent consideration of the challenge on the basis of failure to exhaust administrative remedies. *But see Public Citizen v. NRC*, 901 F.2d 147 (1990).

[110] 387 U.S. 136 (1967).

[111] *Id.* at 148-49.

[112] *Id.*

2. *Ripeness and Preenforcement Review*

Ripeness issues arise most often in the context of preenforcement review of rules. Prior to 1967, agency rules were normally challenged at the time an agency sought to enforce its rule against a particular party. In *Abbott Laboratories v. Gardner*, however, the Supreme Court held that a rule could be challenged before the rule was enforced, if the case were ripe for review. Such preenforcement review is quite common now.

a. No preenforcement review statute. Abbott Laboratories involved a challenge to rules in a context where no statute other than the APA affected the appropriate timing for judicial review. The case dealt with an industry challenge to final rules of the Food and Drug Administration (FDA) requiring that a drug's generic name appear on all labels and other printed material.[115] The Court held that drug manufacturers could challenge the rules immediately, since they would have an immediate and direct impact. The industry would not be required to violate the rules and wait until enforcement proceedings were instituted before they could challenge rules they believed were invalid. The rule was "fit for judicial decision," since the merits of the case involved a pure legal question whether the Food, Drug and Cosmetic Act authorized such rules,[116] and there were no other factors raised by the agency that would justify deferring review.[117]

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[113] *Eagle-Picher Industries, Inc. v. EPA*, 759 F.2d 905, 915 (D.C. Cir. 1985).

[114] *Abbott Laboratories, supra* n. 110, 387 U.S. at 153. *See also State Farm Mutual Auto. Ins. Co. v. Dole*, 802 F.2d 474 (D.C. Cir. 1986), *cert. denied sub nom. New York v. Dole*, 480 U.S. 951 (1987).

[115] *Abbott Laboratories, supra* n. 110, 387 U.S. at 138-39.

In a case decided the same day, the Court held that immediate review of another FDA final rule was not appropriate. In *Toilet Goods Association v. Gardner*,[118] the Court held that an FDA rule providing that the Commissioner may suspend certification of additives where a person has refused access to agency inspection personnel was not ripe for review. While agreeing that the rule was final, and the issue whether the rule was within the agency's power was a legal one, the Court found that these considerations were outweighed by others. The rule had no clear immediate or irreparable impact; it would come into play only if access was refused, and even then no action was mandated. Moreover, the validity of any action on the part of the Commissioner would depend on the particular situation where certification was denied.[119]

In a recent decision from the Supreme Court, the Court reiterated that for a challenge to agency action to be ripe for review, there must be either a substantive rule which as a practical matter requires the plaintiff to adjust his conduct immediately, or some concrete action applying the regulation to the claimant in a fashion that harms or threatens to harm him. In *Lujan v. National Wildlife Federation*,[120] the Court declined to hear a challenge to the Department of Interior's "land withdrawal review program," which was not directed to explicit regulations, but instead appeared to attack a number of changing policies for reviewing classifications of public lands. The Court noted that there was no other source of statutory review authority, and the "concrete effects normally required for APA review" had not been alleged.[121]

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[116] *Id.* at 149.

[117] *Id.* at 148-56.

[118] 387 U.S. 158 (1967).

[119] In a third case decided that day, the Court held several other FDA regulations ripe for review, where they had immediate and substantial impacts, and consideration of the legal issues would not be facilitated if raised in specific factual situations. *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167 (1967).

b. Preenforcement review statutes. Because ripeness is primarily a prudential concept, and thus subject to Congressional direction, Congress has, since *Abbott Laboratories*, provided explicitly for preenforcement review in many regulatory statutes.[122] Under these statutes, petitions for court review of rules may, and in some cases must, be filed within a short, specified time after the rule is promulgated.

The courts generally have treated these time limits as jurisdictional; *i.e.*, they have dismissed petitions for review not brought within the specified time limit,[123] since limits serve "the important purpose of imparting finality into the administrative process, thereby conserving administrative resources."[124] Courts may entertain untimely review petitions in exceptional circumstances, but any exceptions are "carefully scrutinized" to assure that the important policies underlying finality will not be undermined.[125]

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[120] 110 S.Ct. 3177 (1990).

[121] *Id.* at 3190-91. The Court also noted that there was neither "agency action" within the meaning of § 702 of the APA nor "final agency action" within the meaning of § 704.

[122] *See, e.g.*, OSHA Act, 29 U.S.C. §655(f); FTC Act, 15 U.S.C. § 57a(e); Clean Air Act, 42 U.S. § 7607(b); Hobbs Act, 28 U.S.C. § 2342. The Court in *Lujan v. Nat'l Wildlife Fed'n*, *supra* n. 120, expressly distinguished situations where "statutes permit broad regulations to serve as the 'agency action'" and thus be the object of judicial review. 110 S. Ct. at 3190.

Because these statutory preenforcement review provisions generally provide explicitly for review immediately after a rule is promulgated, the question arises whether the validity of a rule may also be challenged in the context of a later enforcement or other proceeding, and if so, which issues are reviewable. In some statutes, Congress expressly prohibited review in enforcement proceedings or at least seemed to do so,[126] but such provisions have been very narrowly interpreted.[127]

Where the statute is not explicit, courts have split on whether and which issues are foreclosed if not raised within statutory review periods. Some courts have distinguished between procedural issues and substantive issues, holding that procedural issues may not be raised in subsequent enforcement proceedings.[128] The District of Columbia Circuit, in *National Labor Relations Board Union v. Federal Labor Relations Authority*,[129] has set out the following structure: (1) Procedural challenges must generally be brought within the statutory review period if one exists;[130] (2) Where a litigant is challenging a lack of statutory authority for the rule, such challenge may be brought in an enforcement proceeding or in another proceeding; and (3) If the substantive challenge involves other than a lack of statutory authority, it may be raised in an enforcement proceeding, or on review of a petition for rulemaking that addresses the particular issues.[131]

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[123] *Eagle-Picher Indus., Inc. v. EPA*, *supra* n.113, 759 F.2d at 911.

[124] *Natural Resources Defense Council v. NRC*, 666 F.2d 595 (D.C. Cir. 1981).

[125] *Eagle-Picher Industries v. EPA*, *supra* n. 113, 759 F.2d at 909-12. Among the exceptions mentioned by the court are inadequate notice, confusion on the law of proper forum, or lack of ripeness.

[126] *See, e.g.*, Clean Air Act, 42 U.S.C. § 7607(b)(1) and (2). Under subsection (1), petitions for review "shall be filed" within 60 days of promulgation of a rule, except if the petition is based "solely on grounds" arising after the 60th day, the petition "shall be filed" within 60 days after such grounds arise. Under subsection (2), action of EPA "with respect to which review could have been obtained" under subsection (1) "shall not be subject to judicial review in civil or criminal proceedings for enforcement." *See also* CERCLA Act, 42 U.S.C. § 9613(a).

[127] *Adamo Wrecking v. United States*, 434 U.S. 275 (1978) (narrowly construing 42 U.S.C. § 7607(b)(2) of the Clean Air Act).

In 1982, the Administrative Conference recommended that "in drafting a statute that provides for adequate preenforcement judicial review of rules, Congress should consider whether to limit the availability of review at the enforcement stage."[132] Four factors were identified as favoring such a limitation: the likelihood that the rulemaking will attract widespread participation; the likelihood that it will involve "complex procedures" or "intensive exploration of the issues"; the likelihood that affected parties will incur substantial and immediate costs in complying; and the need for prompt compliance with the rule on a national or industry-wide basis.[133] The Recommendation urged that:

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[128] *See National Industrial Contractors v. OSHRC*, 583 F.2d 1048 (8th Cir. 1978) (refusing to entertain a procedural challenge to OSHA construction standard after statutory review period, but noting that substantive arguments could be raised at any time); *RSR Corp. v. Donovan*, 747 F.2d 294 (5th Cir. 1984) (procedural challenge foreclosed). *But see Deering Milliken, Inc. v. OSHRC*, 630 F.2d 1094 (5th Cir. 1980) (holding that procedural challenge not precluded after expiration of statutory review period).

[129] 834 F.2d 191, 195-97 (D.C. Cir. 1987).

[130] *Id.* at 195. *See also Eagle-Picher Indus., Inc. v. EPA*, *supra* n. 113.

[131] *NLRB Union v. Federal Labor Relations Authority*, *supra* n. 129, 834 F.2d at 195-97. *See also Public Citizen v. NRC*, 901 F.2d 147 (D.C. Cir. 1990); *Natural Resources Defense Council v. NRC*, 666 F.2d. 595 (D.C. Cir. 1981).

> When Congress decides to limit the availability of judicial review of rules at the enforcement stage, it should ordinarily preclude review only of issues relating to procedures employed in the rulemaking or the adequacy of factual support for the rule in the administrative record. Judicial review of issues relating to the constitutional basis for the rule or the application of the rule to a particular respondent or defendant should be permitted when these issues are raised in subsequent suits or as defenses to subsequent enforcement actions (subject to the principles of collateral estoppel and stare decisis). Judicial review of issues relating to the statutory authority for the rule should be precluded at the enforcement stage only where Congress has concluded that there is a compelling need to achieve prompt compliance with the rule on a national or industry-wide basis.[134]

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[132] Recommendation No. 82-7, "Judicial Review of Rules in Enforcement Proceedings," 1 C.F.R. § 305.82-7. This Recommendation was based on Verkuil, *Congressional Limitations on Judicial Review of Rules: The Jurisprudential Implications*, 1982 ACUS Recommendations & Reports 443, *reprinted as Congressional Limitations on Judicial Review of Rules*, 57 Tulane L. Rev. 733 (1983).

[133] 1 C.F.R. § 305.82-7, ¶ 1(a)-(f).

[134] *Id.*, ¶ 2.

The requirement for the timely filing of review petitions must be distinguished from the issue of ripeness. There may be cases which would not yet be ripe within the statutory review period, or that remain ripe after the period expires, but in general, challenges must be brought within relevant statutory time limits.[135]

Cases involving agency rulemaking have raised the issue of the proper manner for calculating the limitations period for filing petitions for judicial review. In two OSHA cases, the the District of Columbia Circuit held that the 60-day period for filing challenges to OSHA standards begins to run when the standard is *published* in the Federal Register rather than from the date the document is *filed* in the Office of the Federal Register.[136]

Another issue raised by statutory time limits is the effect an agency's reconsideration of a rule may have on interested persons' rights to petition for court review. Courts have held that even if the original period for seeking review of a rule has expired, a new period for seeking review may begin if the agency later reopens issues. In determining whether issues have been reopened, courts look to "the entire context of the rulemaking."[137] In *Public Citizen v. Nuclear Regulatory Commission,*[138] the agency had republished an existing temporary policy statement on nuclear power plant personnel training. Plaintiffs challenged the validity of the action as contrary to the statute. The court held that the NRC had reconsidered the underlying issues in republishing the rule, and that a challenge filed within the newly-started time period could be heard.[139]

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[135] *Eagle-Picher Indus., Inc. v. EPA, supra* n. 113. In that case, petitioners challenged EPA's Hazardous Ranking System under CERCLA, 42 U.S.C. § 9601 *et seq.*, after the 90-day statutory review period had expired, arguing that they were not time-barred because they believed their challenge to the validity of the regulation would not have been ripe during the 90-day period. The court held that generally, "If there is *any* doubt about the ripeness of a claim, petitioners must bring their challenge in a timely fashion or risk being barred." 759 F.2d at 914. Although the court found that the case would have been ripe during the 90-day period, and was thus untimely, it heard the case on the merits because the relationship between ripeness and statutory review provisions had previously been "largely uncharted." *Id.* at 919.

[136] *United Technologies Corp. v. OSHA*, 836 F.2d 52 (2d Cir. 1987) (review of OSHA hazard communications standard); *National Grain & Feed Ass'n v. OSHA*, 845 F.2d 345 (D.C. Cir. 1988) (review of OSHA grain-handling standard). *See also AFL-CIO v. OSHA*, 905 F.2d 1568 (D.C. Cir. 1990) (holding that statutory phrase "prior to the sixtieth day" means that petition filed *on* sixtieth day was too late).

3. *Other Ripeness Issues in Rulemaking*

Ripeness and finality are issues in suits challenging agency inaction or delay.[140] In these cases, there is usually no clear action by an agency that is definitely final, yet that inaction is itself often the gravamen of the complaint.[141]

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[137] *Public Citizen v. Nuclear Regulatory Comm'n,* 901 F.2d 147, 150 (D.C. Cir.1990)("If in proposing a rule the agency uses language that can reasonably be read as an invitation to comment on portions the agency does not explicitly propose to change, or if in responding to comments the agency uses language that shows that it did in fact reconsider an issue, a renewed challenge to the underlying rule or policy will be allowed.").

[138] *Id.*

[139] The court held that the statute required mandatory standards rather than the voluntary policy statement the agency had promulgated.

[140] For a discussion of review of such cases on the merits, *see* Part IV, Ch. 3, *infra.*

[141] *See Telecommunications Research & Action Center v. FCC,* 750 F.2d 70, 75 (D.C. Cir. 1984).

Courts have used ripeness and finality analysis in these cases, and have been willing in some situations to hear the case on its merits, although the standard of review is narrow and the relief granted is usually very limited.[142]

In cases alleging agency delay in acting on petitions for rulemaking or in completing rulemaking proceedings,[143] the issue arises whether there is an agency action that is sufficiently final to be fit for judicial review. The agency oftens argues that until it decides on a final course of action, judicial review is not appropriate. Courts have observed, however, that sometimes "administrative inaction has precisely the same impact on the rights of the parties as denial of relief," and where this is so, "an agency cannot preclude judicial review by casting its decision in the form of inaction rather than in the form of an order denying relief."[144] They have then gone on to consider whether the particular case is ripe for review.[145]

In *Environmental Defense Fund v. Hardin*,[146] the District of Columbia Circuit held that EPA's failure to act on a request for interim suspension of DDT was "tantamount to an order denying suspension."[147] Such action was sufficiently final and resulted in sufficient hazard to the public to make the challenge ripe for judicial resolution.[148]

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[142] *See* Part IV, Ch. 3, *infra*.

[143] If the agency has taken action in rejecting the request for rulemaking or in deciding not to issue a standard, finality questions would not ordinarily arise, but issues of reviewability are present. *See* discussion *infra*, Part IV, Ch. 3(B)(1).

[144] *Environmental Defense Fund v. Hardin*, 428 F.2d 1093, 1099 (D.C. Cir. 1970).

[145] *Id.*; *Public Citizen Health Research Group v. FDA*, 740 F.2d 21 (D.C. Cir. 1984).

[146] *Id.*

[147] *Id.*, 428 F.2d at 1099.

A similar analysis has been used in cases challenging an agency's delay in issuing a rule. *Public Citizen Health Research Group v. Food and Drug Administration*[149] involved alleged FDA delay in requiring aspirin products to carry a warning about Reye's Syndrome. Because FDA had not yet decided the labeling issue,[150] the court considered whether the issue was "sufficiently final to be fit for review."[151] Although the court refused to treat the agency's tentative conclusions as final action, it noted that "at some point administrative delay amounts to a refusal to act, with sufficient finality and ripeness to permit judicial review."[152] While not finding that to be the case in this instance, the court did remand the case to the district court for determination whether the agency's delay was "unreasonable."[153]

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[148] Although the court found the case ripe for review, it concluded that "meaningful review" was impossible because of the absence of any record of agency action; it therefore remanded to the agency for a "statement of reasons for [its] silent but effective refusal to suspend . . . ." *Id.* at 1099-1100.

[149] 740 F.2d 21 (D.C. Cir. 1984).

[150] FDA had earlier concluded that aspirin products should be labelled, reversed itself and not published a draft proposed rule on the issue, and then published an advanced notice of proposed rulemaking saying that it was "considering proposing" a rule. No further action was taken. 740 F.2d at 24-27.

[151] *Id.* at 30.

[152] *Id.* at 32.

[153] *Id.* at 35. *See also* discussion of this case, *infra*, in Part IV, Ch. 3.

PART IV: JUDICIAL REVIEW OF AGENCY RULEMAKING

CHAPTER 2

THE SCOPE OF JUDICIAL REVIEW

Rulemaking is conducted within a legal framework that rests on statute, but rulemaking procedure has been significantly influenced by court-made law. This chapter examines perhaps the most important court-made law on rulemaking -- that interpreting the scope of judicial review of agency rules.

A. Scope of Review - General Provisions

The scope of judicial review is the standard by which a court will judge the validity of the agency action in review proceedings. Unless the enabling statute for a particular regulatory program specifies a different standard, the provisions of the Administrative Procedure Act govern. While enabling statutes occasionally provide for a "substantial evidence" test or some other standard in court review of agency rules,[1] more often, the enabling statute either contains no specific provision on scope of review, or it expressly incorporates the APA provisions. The "Scope of Review" section of the APA is 5 U.S.C. §706, which provides:

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[1] *See, e.g.*, OSH Act, 29 U.S.C. § 655(f); Medical Device Amendments, 21 U.S.C. §360g(c).

The Scope of Judicial Review

> Scope of review
>
> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--
>
> (1) compel agency action unlawfully withheld or unreasonably delayed; and
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be--
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right, power, privilege, or immunity;
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance of procedure required by law;
>
> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
>
> (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.
>
> In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

In the review of informal rulemaking, sections 706(1) and 706(2)(A), (B), (C), and (D) are applied most often. Subsections

706(2)(E) and (F), providing for "substantial evidence" and *de novo* review, are not applicable to informal rulemaking unless they are expressly adopted in an agency enabling statute. Each of the relevant subsections of section 706 will be treated separately in this chapter.

1. APA: Section 706(1): "agency action unlawfully withheld or unreasonably delayed"

This subsection, authorizing a court to "compel agency action unlawfully withheld or unreasonably delayed," is increasingly being invoked in suits challenging agency inaction in rulemaking, often in conjunction with other statutory provisions.[2] These suits typically allege unreasonable agency delay in completing rulemaking, agency refusal to initiate rulemaking, or an agency refusal to issue a rule, in whole or in part, when rulemaking is completed.

In 1985 the Supreme Court held, in *Heckler v. Chaney*,[3] that court review is presumptively unavailable where an agency refuses to undertake an *enforcement* action. Although the reach of *Chaney* was initially uncertain, it appears that courts generally will not apply that decision to agency inaction in rulemaking. They typically do, however, apply a highly deferential standard in reviewing challenges alleging that agency rulemaking action is being "unlawfully withheld or unreasonably delayed." The reasons for the courts' deferential approach and the recent case law on judicial review of challenges to agency inaction are treated more fully in Chapter 3, below.

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[2] *E.g.*, 5 U.S.C. § 555(b) ("within a reasonable time, each agency shall proceed to conclude a matter presented to it"). Some enabling statutes expressly provide for court review of agency inaction in certain circumstances. *See, e.g.*, 49 U.S.C. § 10326(b)(2)(ICC statute), *applied in Western Fuels-Illinois, Inc. v. ICC*, 878 F.2d 1025 (7th Cir. 1989).

[3] 470 U.S. 821 (1985).

2. APA: Section 706(2)(A): "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"

This standard of review, commonly referred to as the "arbitrary or capricious" test, is the traditional standard applied by courts in reviewing agency rules promulgated after informal rulemaking. While the substantive rationality of an agency rule has been the main focus of review under the arbitrary or capricious test, the test also has become a "catch all" provision, "picking up . . . administrative misconduct not covered by the other more specific paragraphs [of section 706]."[4] Courts applying the test usually focus on the following three components of review under this standard: (1) whether the rulemaking record supports the factual conclusions upon which the rule is based; (2) the "rationality" or "reasonableness" of the policy conclusions underlying the rule; and (3) the extent to which the agency has adequately articulated the basis for its conclusions. While procedural issues and the validity of the agency's statutory interpretation are often also part of arbitrary or capricious review, these will be discussed below with respect to separate subsections of Section 706 of the APA.[5]

The meaning of the terms "arbitrary," "capricious," "abuse of discretion" and "not in accordance with law" is by no means self-evident,[6] and reviewing courts' interpretations of this subsection have changed over time. Until the 1970s, the prevailing guide was that stated by the Supreme Court in the pre-APA case of *Pacific States Box & Basket Co. v. White*,[7] as follows: "[W]here the regulation is within the scope of authority legally delegated, the presumption of the existence of facts justifying its specific exercise attaches . . . ."[8] However, in 1971, the Supreme Court ushered in a new era of closer court scrutiny of agency rules in the landmark decision, *Citizens to Preserve Overton Park v. Volpe*.[9]

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[4] *Association of Data Processing Serv. Orgs., Inc. v. Board of Governors*, 745 F.2d 677, 683 (D.C. Cir. 1984).

[5] *See* discussion *infra*, subs. (4), (5).

In *Overton Park*, the Secretary of Transportation, after a "quasi-legislative" hearing, had approved federal funds for construction of a highway through a park. The Court found that section 706(2)(A) (*i.e.*, the arbitrary or capricious test) was the applicable test for review, and it construed the test as follows:

> To make this finding [whether the decision was arbitrary or capricious], the court must consider whether the decision was based on a consideration of the relevant factors and whether there had been a clear error of judgment . . . . Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency.[10]

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[6] *See Weyerhaeuser Co. v. Costle*, 590 F.2d 1011, 1024 (D.C. Cir. 1978) (discussing vagueness of the formulations in the various clauses in § 706(2), but especially § 706(2)(A)).

[7] 296 U.S. 176 (1935).

[8] *Id.* at 186.

[9] 401 U.S. 402 (1971).

[10] *Id.* at 416 (citations omitted).

This language, although written in a case involving informal adjudication rather than rulemaking, has been frequently relied on by courts in reviewing informal rulemaking.[11]

Overton Park's language is not without ambiguity. It seems simultaneously to reflect both an intrusive and a deferential attitude.[12] Moreover, there has subsequently been extensive discussion in cases and commentary about the differences between the arbitrary or capricious test, as described in *Overton Park*, and the "substantial evidence" test normally applied to adjudicatory decisions, formal rulemakings, and sometimes to rulemaking under particular enabling statutes. A number of courts and commentators have concluded that, at least when applied to court review of factual conclusions by agencies, the distinction between the substantial evidence and the arbitrary or capricious tests is "largely semantic."[13] Thus, in *Consumers Union Inc. v. FTC*,[14] involving review of an FTC rule relating to the sale of used cars, the District of Columbia Circuit concluded that "in the context of the APA, the substantial evidence test (which is applied only to formal adjudication and formal rulemaking . . .) and the arbitrary or capricious test (which governs review of *all* proceedings . . .) 'are one and the same' insofar as the requisite degree of evidentiary support is concerned."[15] The court held that the standard, as applied to the FTC rulemaking, demanded "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion,"[16] and it went on to uphold the rule.

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[11] The close scrutiny called for by *Overton Park* became known as the "hard look" doctrine, *see* Rodgers, *A Hard Look at Vermont Yankee: Environmental Law Under Close Scrutiny*, 67 Geo. L. J. 699, 704-05 (1979).

[12] Thus the court spoke both of "searching and careful" inquiry into the facts and a "narrow" "ultimate standard of review."

[13] *Association of Data Processing*, *supra* n. 4, 745 F.2d at 684 (and cases cited therein). *See* Note, *Convergence of the Substantial Evidence and Arbitrary and Capricious Standards of Review During Informal Rulemaking*, 54 Geo. Wash. U. L. Rev. 541 (1986). The view seems to have been first stated in Scalia & Goodman, *Procedural Aspects of the Consumer Product Safety Act*, 20 U.C.L.A. L. Rev. 899, 935 n. 138 (1973).

[14] 801 F.2d 417 (D.C. Cir. 1986).

a. Significant recent Supreme Court decisions applying the arbitrary or capricious test. In the early 1980s, the Supreme Court revisited the question of the scope of arbitrary or capricious review in two rulemaking cases. *Baltimore Gas & Electric Co. v. NRDC*[17] involved review of a series of generic rules issued by the Nuclear Regulatory Commission (NRC) to evaluate the environmental effects of a nuclear power plant's fuel cycle.[18] The District of Columbia Circuit had held the NRC rules to be arbitrary or capricious, finding that the agency made certain unsupported assumptions in issuing the rules and failed to factor into its decisional process certain factual uncertainties.[19] The Supreme Court reversed, noting that the NRC was making "predictions, within its area of special expertise, at the frontiers of science" and stating that the reviewing court "must generally be at its most deferential" when examining this kind of scientific determination.[20] The Court further concluded that NRC's assumptions were "within the bounds of reasoned decisionmaking" and that the agency had "considered the relevant factors and articulated a rational connection between the facts found and the choice made."[21] "If the agency meets these requirements," the Court admonished, "it is not our task to determine what decision we, as Commissioners, would have reached."[22]

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[15] *Id.* at 422 (*quoting Association of Data Processing Serv. Orgs., supra* n. 4).

[16] *Id.* The relevant statutory provision is 15 U.S.C. § 57a(e)(3)(A), which authorizes a "hybrid" form of rulemaking procedure.

[17] 462 U.S. 87 (1983).

[18] This case was a later stage of the proceeding that first reached the Supreme Court in *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519 (1978).

[19] *See Natural Resources Defense Council, Inc. v. NRC*, 685 F.2d 459 (D.C. Cir. 1982).

In 1984, the Supreme Court again applied the arbitrary or capricious test, in *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*[23] This time, however, it reversed the agency's rulemaking decision. At issue in *State Farm* was the National Highway Traffic Safety Administration's (NHTSA's) rescission of a rule, issued by a prior administration, requiring passive restraints (such as automatic seatbelts and airbags) in new cars. The Supreme Court first addressed the appropriate scope of judicial review of the rule rescission and concluded that the agency's enabling statute contemplated review under the APA's arbitrary or capricious standard.[24] The Court rejected appellant's argument that the rescission of a rule should be judged by the same deferential standard as review of an agency's refusal to promulgate a rule in the first place.[25]

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[20] 462 U.S. at 103.

[21] *Id.* at 104-05.

[22] *Id.* at 105. *See also Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 109 S. Ct. 1851, 1861 (1989) (an agency must have "discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find the contrary views more persuasive").

[23] 463 U.S. 29 (1983).

[24] *Id.* at 41.

The Supreme Court then considered the meaning of the arbitrary or capricious standard as applied to a rule rescission. Rejecting the government's argument that this requires "no more than the minimum rationality" needed for a statute to withstand a due process challenge, the Court held that the presumption of regularity afforded an agency in its regulatory activities was not equivalent to the "presumption of constitutionality" afforded legislation enacted by Congress.[26] The Court said that the scope of review under the arbitrary or capricious standard is "narrow and a court is not to substitute its judgment for that of the agency."[27] The Supreme Court elaborated as follows:

> Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.[28]

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[25] *Id.* "[T]he revocation of an extant regulation is substantially different than a failure to act," the Court said, in that revocation "constitutes a reversal of the agency's former views as to the proper course [of regulation]." The Court accordingly held that an agency "changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when the agency does not act in the first instance." *Id.* at 42.

[26] *Id.* at n.9.

[27] *Id.* at 43.

[28] *Id.* The Court cited *SEC v. Chenery Corp.*, 332 U.S. 194 (1947), for the proposition that the reviewing court "should not attempt itself to make up for such deficiencies [in the agency explanation]".

Applying this standard, the Court decided that NHTSA had acted arbitrarily in rescinding the earlier rule without any consideration of the mandatory air bag option.[29] The Court further held that the record was not sufficient to enable it to conclude that the rescission of the passive restraint requirement was the product of reasoned decisionmaking.[30] While the Court conceded that "an agency's view of what is in the public interest" may change, "either with or without a change in circumstances,"[31] it insisted that an agency changing its course "must supply a reasoned analysis." The Court remanded the matter to NHTSA for further consideration.[32]

The Supreme Court in 1986, in *Bowen v. American Hospital Association*,[33] reaffirmed its conclusion in *State Farm* that an agency regulation is not entitled to the same presumption of regularity as is a statute challenged under the due process clause.[34] The Supreme Court vacated a rule issued by the Department of Health and Human Services dealing with health care for handicapped infants, stating that deference to agencies' decisions had "not come so far" that a regulation would be upheld whenever it is possible to "conceive a basis" for administrative action.[35] The Court asserted:

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[29] 463 U.S. at 46-48.

[30] *Id.* at 51-56.

[31] *Id.* at 57. The Court's alternative rationale for the remand was the agency's complete failure to justify the promulgation of the "airbags only" rule.

[32] *Id.*

[33] 476 U.S. 610 (1986).

[34] *Id.* at 627. The main issue in the case was whether the regulation was authorized by section 504 of the Rehabilitation Act of 1973, 29 U.S.C. §794; the Court, with four Justices dissenting, held that the regulation was not authorized. *Id.*

> Our recognition of Congress' need to vest administrative agencies with ample power to assist in the difficult task of governing a vast complex industrial Nation carries with it the correlative responsibility of the agency to explain the rationale and factual basis for its decision, even though we show respect for the agency's judgment in both.[36]

b. *Courts of Appeals review after* *__State Farm__*. These Supreme Court decisions have been influential in defining lower court review under the arbitrary or capricious standard. For example, the principles of *State Farm* were followed soon after by the District of Columbia Circuit in *International Ladies' Garment Workers' Union v. Donovan*,[37] which involved a challenge to the Department of Labor's rescission of restrictions on "home work" in certain industries under the Fair Labor Standards Act.[38] The District of Columbia Circuit applied the arbitrary or capricious standard of review to the rescission, characterizing the agency's action as "a classic example of an agency attempt to modify a longstanding policy by rescinding regulations embodying that policy."[39] The court stated: "We cannot discern any rational basis for being less circumspect in reviewing the rescission of a regulation that has been uniformly supported since its adoption forty years ago, than the Supreme Court was in reviewing rescission of a highly controversial regulation [the NHTSA passive restraint rule]."[40] The court of appeals then examined the Secretary of Labor's rationale for rescinding the home work rule and concluded that the Secretary had failed to address known or reasonable options and to explain why such options were rejected.[41] This constituted a complete failure to satisfy the "quintessential aspects of reasoned decisionmaking," the court said, and was the "primary basis" for its decision to vacate the agency action.[42]

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[35] 476 U.S. at 626, citing *Motor Vehicles Mfrs. Ass'n, supra* n. 23.

[36] *Id.* at 627.

[37] 722 F.2d 795 (D.C. Cir. 1983), *cert. denied*, 469 U.S. 820 (1984).

[38] Acting under the Fair Labor Standards Act, 29 U.S.C. §§ 201-219, the Secretary of Labor for many years had in effect restrictions on employment of workers in their homes. In 1981, the Secretary rescinded the homeworkers regulations in the knitted outwear industry. This decision was challenged by certain employers and associations, unions and state labor enforcement officials. 722 F.2d at 799.

[39] *Id.* at 812.

In another case involving a NHTSA highway safety rule, *Center for Auto Safety v. Peck*,[43] the District of Columbia Circuit upheld a rule that modified past policy by reducing minimum performance standards for automobile bumpers.[44] In discussing the standard of review to be applied, the court emphasized that it was not to substitute its judgment for that of the agency, particularly where the agency is called on to weigh the costs and benefits of alternative policies, since these decisions "epitomize the types of decisions that are most appropriately entrusted to the expertise of an agency."[45] The court rejected the argument that a reversal of longstanding agency policy requires heightened judicial scrutiny.[46] The court, citing *State Farm*, ruled that the same test on review applies "to the rescission or modification of a rule as to its initial promulgation,"[47] and that an agency action is arbitrary or capricious only when there is an absence of "overall rational support," even if there are 'uncertainties, analytic imperfections, or even mistakes."[48] Since NHTSA's conclusions were "within the range of those that a reasonable person could derive from the evidence presented," the court of appeals affirmed the agency action.[49]

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[40] *Id.* at 814.

[41] *Id.* at 818.

[42] *Id.* *See also AFL-CIO v. Brock*, 835 F.2d 912 (D.C. Cir. 1987) (reversing the Department of Labor's action altering prior policy regarding the minimum wage for foreign agricultural workers, for lack of a reasond explanation).

[43] 751 F.2d 1336 (D.C. Cir. 1985).

[44] NHTSA modified its rule, issued under the National Traffic and Motor Vehicle Safety Act, 15 U.S.C. §§ 1381-1431, and the Motor Vehicle Information and Cost Savings Act, 15 U.S.C. §§ 1901-91, so that "lighter, less protective, and less costly bumpers" would satisfy the safety standard. 751 F.2d at 1338.

Thus, the Supreme Court's *State Farm* decision had a major impact on judicial review of deregulation during the Reagan years. Its longterm significance is less clear. One commentator has suggested that the decision "expressly endorses the primary elements, both substantive and procedural, of the hard-look doctrine," and is "designed to require decisionmaking that is highly structured, that identifies goals in a way that conforms to the governing statute, and that selects methods of achieving those goals in a logical manner."[50]

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[45] 751 F.2d at 1342.

[46] *Id.* at 1342-43.

[47] *Id.* at 1343.

[48] *Id.* at 1370.

[49] *Id.* The court, in support of its conclusion that NHTSA's action was not arbitrary or capricious, described the rulemaking as being an "enterprise of much difficulty and scope," which was pursued "through a methodology that was sensible," and during which NHTSA "responded to, and often accommodated, every major criticism and suggestion." *Id.*

In summary, although it is difficult to draw clear conclusions from often inconsistent court opinions on arbitrary or capricious review, these generalizations are possible:

1. A reviewing court normally will not substitute its judgment for that of the agency in making factual conclusions so long as the agency's conclusions have a substantial basis in the record; this is particularly true where the subject matter is technical, on the frontiers of science, or involves a considerable exercise of agency expertise.

2. A reviewing court generally will defer to agency policy judgments, so long as they are "rational" or "reasonable" -- concededly vague terms -- and they are the product of what has traditionally been called "reasoned decisionmaking." To demonstrate that reasoned decisionmaking has taken place, an agency must explain in its statement of basis and purpose why it has rejected significant alternative options, why it has departed from past policies, and how its conclusions are derived from the facts in the record.

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[50] Sunstein, *Deregulation and the Hard-Look Doctrine*, 1983 up. Ct. Rev. 177, 210. For another view, *see* Breyer, *Judicial eview of Questions of Law and Policy*, 38 Admin. L. Rev. 363, 88 (1986) (questioning the ability of judges "to supervise the ast realm of substantive agency policymaking").

3. A reviewing court will apply these same principles to agency deregulation, with emphasis placed on the need for the agency to fully explain why the deregulatory action is being taken, why prior policy is being revised, and whether less dramatic alternatives were considered and rejected.

If agency rulemakers give careful attention to the factual underpinnings of the rule, and reach their conclusions by means of "reasoned decisionmaking," this should ordinarily be enough to withstand claims that the agency was arbitrary or capricious in making its determination of fact, discretion or policy.

3. APA: Section 706(2)(B): "contrary to constitutional right, power, privilege or immunity"

This clause states the self-evident proposition that, when reviewing agency action, including agency rules, the courts must decide constitutional challenges. While the due process clauses of the fifth and fourteenth amendments theoretically apply to government rulemaking, in practice they play little direct role in judicial review of rules. The reason is that the APA and many enabling statutes prescribe relatively detailed public participation procedures for rulemaking, and agency rulemaking that conforms to those procedures will almost always meet constitutional mandates as well.[51] It should be emphasized, however, that constitutional objections may be raised to provisions in the underlying statute that may have significant impact on rulemaking under that statute. For example, where the underlying statute contains an unconstitutional legislative veto, the agency's authority to issue rules would be eliminated, if the veto were held non-severable.[52]

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[51] *See Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519, 542 n.16 (1978). Of course, procedural issues arising under the APA and enabling satutes, such as adequacy of notice, are predicated ultimately on constitutional principles of due process.

4. *APA: Section 706(2)(C): "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right"*

This clause expresses the familiar proposition that an agency's action must be within the authority delegated to it by the legislature. Reviewing courts are often faced with contentions that agency rules are beyond the agency's legal authority or that the agency incorrectly interpreted a statutory provision in issuing a rule.[53] In dealing with these issues, courts are required to determine how much deference they will give to an agency's interpretation of its governing statutes.[54]

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[52] *See Alaska Airlines Inc. v. Brock*, 480 U.S. 678, 107 S. Ct. 1476 (1987) (upholding rulemaking authority under the Airline Deregulation Act as severable from unconstitutional legislative veto). *See also* discussion *supra*, Part I (C).

[53] The question of the scope of agency authority also is relevant to other rulemaking issues, such as whether the rule is question is a "legislative" or "non-legislative" rule. *See* discussion *supra*, Part II, Ch. 1(D).

[54] The Administrative Conference has addressed the issue of court review of agency statutory interpretations several times. See Recommendation No. 89-5, "Achieving Judicial Acceptance of Agency Statutory Interpretations," 1 C.F.R. § 305.89-5. *See also* Recommendation No. 79-6, "Elimination of the Presumption of Validity of Agency Rules and Regulations in Judicial Review, as Exemplified by the Bumpers Amendment," 1979 ACUS Recommendations & Reports 33; Recommendation No. 81-2, "Current Versions of the Bumpers Amendment," 1981 ACUS Recommendations & Reports 7. The Bumpers Amendment, which was never enacted, would have modified

In determining the amount of deference due agency statutory constructions, courts often are required to disentangle the legal, factual and policy issues involved in an agency's promulgation of a rule. The difficulty of this task is illustrated by the Supreme Court's review of OSHA's "benzene" rule.[55] OSHA had issued a rule regulating the carcinogen benzene to a permissible level of one part benzene per million parts of air on the basis of what the agency termed a "policy" judgment, that in regulating carcinogens no exposure level could be considered safe. Accordingly, OSHA set its standard at the lowest technologically feasible level that would not impair the viability of the regulated industries.[56] The Supreme Court vacated OSHA's standard, concluding that OSHA failed to show by substantial evidence that benzene constituted a "significant risk" at the current level of exposure.[57] The plurality opinion by Justice Stevens relied particularly on the statutory definition of "occupational safety and health standard" as one that was "reasonably necessary or appropriate to provide safe or healthful employment,"[58] and interpreted this provision as requiring a finding of "significant health risk" before OSHA was authorized to regulate.[59] The Supreme Court, in effect overruling the agency's *policy* basis for its rule, viewed the issue as a *legal* question and reversed the

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the standard for court review of agency interpretations, by reducing or eliminating judicial deference to such interpretations.

[55] *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607 (1980).

[56] *Id.* at 613.

[57] *Id.* at 653.

[58] 29 U.S.C. § 652(8), discussed *id.* at 639-46.

[59] 448 U.S. at 614-15.

agency's interpretation of its enabling statute. The Supreme Court refused to defer to the agency's interpretation of its enabling statute in light of the inconsistencies in OSHA's position and the statute's legislative history.

In 1984, the Supreme Court addressed more generally the scope of court review of agency legal determinations, in *Chevron USA Inc. v. NRDC.*[60] This case involved EPA rules regulating emissions under the Clean Air Act. The Supreme Court upheld the EPA's interpretation of the term "source", as used in the Act, to allow plant-wide regulation of emission sources as a single source. In agreeing with EPA's construction of the statute, the Court set forth a two-part test for review of agency statutory interpretations:

> (1) Has Congress "directly" spoken to the "precise" question at issue? "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress"[61]; and
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> (2) If Congress has not done so, and the statute is "silent or ambiguous with respect to the specific issue," then the question for the court is whether "the agency's answer is based on a permissible construction of the statute."[62] Legislative regulations of the agency are

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[60] 467 U.S. 837, *reh. denied*, 468 U.S. 1227 (1984). *See also* discussion *supra*, Part I(B).

[61] *Id.* at 842-43. On this point, the Court stated that the "judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent." *Id.* at 843 n.9.

[62] *Id.* at 843.

"given controlling weight unless they are arbitrary, capricious or manifestly contrary to the statute."[63]

The Court said further that --

> [i]f Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. . . . Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.[64]

The Court elaborated, stating that "[j]udges are not experts in the [technical] field, and are not part of either political branch of the Government."[65] By contrast, agencies are part of the executive branch of the government, which appropriately makes "policy choices -- resolving the competing interests which Congress itself either inadvertently did not resolve, or intentionally left to be resolved by the agency charged with the administration of the statute in light of everyday realities."[66]

The Supreme Court has subsequently applied *Chevron's* two-part test in reviewing agency statutory interpretations, and some differences of views on the proper application of *Chevron* have emerged among the Justices. In *Chemical Manufacturers Association v. Natural Resources Defense Council*,[67] a 1985 case involving EPA policy on variances from toxic pollutant effluent limitations under the Clean Water Act, a majority of the Supreme Court followed the *Chevron* analysis and upheld the agency's interpretation of the Act. However, four Justices dissented, refusing to defer to EPA's interpretation, which they believed to be inconsistent with the clear intent of Congress.[68]

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[63] *Id.* at 844.

[64] *Id.* at 843-44. This language has led some commentators to describe the *Chevron* test in terms of three steps, adding as an issue whether the statute delegates authority to the agency to fill in the gaps Congress left in the statute. *See Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 412 (7th Cir. 1987) ("Different statutes transfer different sorts of implementing authority to agencies, and therefore there is not one but many standards of deference when agencies interpret statutory language.")

[65] 467 U.S. at 865.

[66] *Id.* at 865-66.

In *Immigration and Naturalization Service v. Cardoza-Fonseca*,[69] decided in 1987, the Court's majority refused to defer to an INS statutory interpretation, saying that *Cardoza-Fonseca* involved "a pure question of statutory construction [which is] for the courts to decide."[70] Justice Scalia, although concurring in the result, stated that the majority "badly misinterpreted" *Chevron* by implying that courts may substitute their interpretation of a statute for that of the agency whenever they face a pure question of statutotry construction.[71]

The disagreement among Supreme Court justices on the proper application of the *Chevron* deference test surfaced again in *Dole v. United Steelworkers of America*,[72] where the Court reversed the Office of Management and Budget's interpretation of the Paperwork Reduction Act,[73] relying on the language of the Act, the object and structure of the Act as a whole, and the "traditional canons of construction."[74] The Court declined to defer to OMB's interpretation of the Act's term "information collection request" to include third-party disclosure requirements, finding a clear Congressional intent to the contrary.[75] Dissenting Justices questioned the majority's failure to adhere strictly to the *Chevron* doctrine.[76]

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[67] 470 U.S. 116 (1985).

[68] *Id.* at 152-65.

[69] 480 U.S. 421 (1987). The case involved the validity of an INS interpretation of the Immigration and Nationality Act relating to the grant of asylum to refugees.

[70] 480 U.S. at 446, 448.

[71] *Id.* at 455.

[72] 110 S. Ct. 929, 934, 935 (1990).

Although the Supreme Court's *Chevron* decision has had an impact on judicial review of agency statutory interpretations,[77] it is not surprising, in light of the later Supreme Court cases, that lower court decisions no longer consistently show deference to agency statutory interpretations.[78] Sometimes *Chevron* is followed.[79] However, in other cases, the lower courts do not apply a strict reading of *Chevron*.[80]

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[73] 44 U.S.C. § 3501 *et seq.*

[74] 110 S. Ct. at 934.

[75] *Id.* at 938.

[76] *Id.* at 938-40.

[77] An empirical study done for the Administrative Conference concluded that "*Chevron* significantly altered the proportion of agency cases affirmed by the appellate courts over a period of time during which judicial memberships and preferences apparently were stable." *See* Schuck & Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law* 70 (1989) (to be published in Duke L.J.)

[78] D.C. Circuit Chief Judge Wald has observed:

> [O]ur circuit initially took a fairly rigid approach to [Chevron], deferring to agencies in a wide array of situations. . . . .
>
> Today, our court seems to be inching back towards a more balanced stance, allowing greater space for judicial legal interpretations and moving away from complete deference to the agency. In part we are emboldened by the Supreme Court's decision . . . in *INS v. Cardoza-Fonseca* . . . .

In 1989, the Administrative Conference addressed the extent to which *Chevron* deference should be accorded to various "formats" of agency interpretations, including regulations, adjudicatory opinions, manuals, briefs, policy statements and the like.[81] In its Recommendation, the Conference proposed that an agency intending to develop definitive interpretations should use rulemaking, formal adjudication, or other procedures "authorized by Congresss for, and otherwise appropriate to," the development of definitive interpretations. However, where the agency interprets its statute without using procedures authorized by Congress for

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The Contribution of the D.C. Circuit to Administrative Law, 40 Admin. L. Rev. 507, 529-30. *See also* Breyer, *Judicial Review of Questions of Law and Policy*, 38 Admin. L. Rev. 363, 380-81 (1986) (predicting "varied approaches" by courts in applying *Chevron*). For a useful summary of the cases and literature spawned by *Chevron*, *see* Jordan, *Deference Revisited: Politics as a Determinant of Deference Doctrine and the End of the Apparent* Chevron *Consensus*, 68 Nebr. L. Rev. 454 (1989).

[79] *See, e.g., Chemical Waste Management, Inc. v. EPA*, 873 F.2d 1477, 1482 (D.C. Cir. 1989) (it is "now clearly the prerogative of the agency . . . to bring its own expertise to bear upon the resolution of ambiguities in the statute that Congress has charged it to administer.")

[80] *See, e.g., Costello v. Agency for Int'l Dev.*, 843 F.2d 540, 542 (D.C. Cir. 1988) (court refused to endorse the Foreign Service Grievance Board's interpretation of the statutory term "grievance," relying expressly on *Cardoza-Fonseca* as support for its observation that the case presented "a pure question of statutory construction"); *American Mining Congress v. EPA*, 824 F.2d 1177 (D.C. Cir. 1987) (setting aside EPA rule amending its definition of "solid waste" under CERCLA).

[81] Recommendation No. 89-5, "Achieving Judicial Acceptance of Agency Statutory Interpretations," 1 C.F.R. § 305.89-5. The Recommendation is based on Anthony, *Which Agency Interpretations Should Bind Citizens and Courts?*, 7 Yale J. on Reg. 1 (1990), *reprinted in* 1989 ACUS Recommendations & Reports 369.

the development of "definitive agency statutory interpretations," the agency may expect only that these interpretations will be entitled to "such special consideration as their nature and the circumstances of their adoption warrant."[82]

5. APA: Section 706(2)(D): "without observance of procedure required by law"

This clause requires reviewing courts to set aside agency rules for failure to adhere to legally required procedures. This provision must be considered, however, in conjunction with the last directive in section 706: "due account shall be taken of the rule of prejudicial error."

Clause (D) forms the basis for the third main prong of judicial review of rulemaking: review of the procedures used by the agency. Thus, when an agency violates a procedure mandated by the APA, an applicable statute, its own regulations, or a court,[83] and the violation is prejudicial to a participant in the process, the rule must be set aside, and normally remanded to the agency for a corrective proceeding. The following are the main legal sources for procedural requirements, the violation of which may lead to court reversal of the agency rule:

a. *The APA.* In the context of informal rulemaking, this refers to the provisions in section 553 requiring notice, comment, a statement of basis and purpose, a delayed effective date, and under section 552, publication of the rule.[84] There have been numerous challenges to agency rules based on an agency having violated APA procedural requirements.[85]

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[82] Recommendation No. 89-5.

[83] However, the authority of a court to mandate procedures beyond those in the APA was sharply curtailed in *Vermont Yankee Nuclear Power Corp. v. NRDC, see* discussion *infra,* subs. (5)(d).

b. *Other statutes.* Many regulatory enabling statutes contain additional procedures for informal rulemaking. These too must be followed and may constitute a basis for a court's vacating the rule. In addition, the government-wide procedural statutes, such as the Government in the Sunshine Act, the Federal Advisory Committee Act and Paperwork Reduction Act, as well as various executive orders, impose procedures on agencies that are applicable to rulemaking.[86] It should be noted, however, that the Regulatory Flexibility Act contains a provision on judicial review, providing among other things, that a regulatory flexibility analysis prepared under that statute and the "compliance or noncompliance of the agency" with its provisions "shall not be subject to judicial review."[87] Similarily, Executive Order No. 12,291 provides that it is intended to improve the internal management of the federal government and it is not intended "to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person."[88] Executive Order No. 12,498 contains an identical provision.[89]

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[84] *See* discussion, *supra*, Part II, Ch. 1, on the APA procedures for rulemaking, as well as Part III, generally.

[85] These cases are discussed throughout this Guide.

[86] These generic requirements are discussed *supra*, Part II, Ch. 3, and Part III, Ch. 2.

[87] 5 U.S.C. § 611. *See* Verkuil, *A Critical Guide to the Regulatory Flexibility Act*, 1982 Duke L.J. 213, 259-60.

[88] Exec. Order No. 12,291, § 9 (cross-referencing § 4). The Administrative Conference has endorsed this limitation. *See*

c. *The agency's procedural regulations.* Many agencies have procedural regulations governing rulemaking. It is a well-established principle that, if prejudicial, "an agency's failure to follow its own regulations is fatal to the deviant action."[90]

This principle is illustrated by *Rodway v. Department of Agriculture.*[91] In *Rodway,* the Department of Agriculture had promulgated a regulation making APA procedures applicable to otherwise exempt rules relating to public property, loans, trants, benefits or contracts. It later issued a food-stamp-related rule without using APA procedures. The reviewing court found that, even though the regulation fell within an exemption from APA procedural requirements, it was invalid because the Department failed to follow its own procedural rules.[92]

The principle that an agency must follow its own regulations, whether mandated by law or not, may not apply, however, in cases where procedural regulations were not

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Recommendation No. 88-9, "Presidential Review of Agency Rulemaking," 1 C.F.R. § 305.88-9, ¶ 7 ("The presidential review process should be designed to improve the internal management of the federal government and should not create any substantive or procedural rights enforceable by judicial review.") Others have argued for limited judicial review. *See, e.g.,* Raven-Hansen, *Making Agencies Follow Orders: Judicial Review of Agency Violations of Executive Order 12,291,* 1983 Duke L.J. 285.

[89] Exec. Order No. 12,498, §5.

[90] *Way of Life Television Network, Inc. v. FCC,* 593 F.2d 1356, 1359 (D.C. Cir. 1979). This principle stems from two earlier Supreme Court cases, *Vitarelli v. Seaton,* 359 U.S. 535, 539 (1959); *Service v. Dulles,* 354 U.S. 363 (1957).

[91] 514 F.2d 809 (D.C. Cir. 1975).

[92] *Id.* at 814.

intended to benefit the aggrieved party or to vest rights in the public.[93]

d. *Procedural requirements imposed by courts.* In the 1970s, courts began to require use of procedures in addition to the APA's minima, either to provide additional degrees of fairness to participants or to improve the record of the proceeding in aid of the courts' judicial review responsibilities. This development stemmed in part from the difficulty courts faced in understanding and digesting the large, technical records produced by many rulemaking proceedings. It was this difficulty which led then-Chief Judge Bazelon of the District of Columbia Circuit to favor procedural review strongly over substantive review.[94]

However, the Supreme Court in 1978 decided *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council,*[95] and came down squarely *against* close judicial scrutiny of agency rulemaking procedures with a concomitant power to require additional procedures. In reversing the District of Columbia Circuit's decision[96] that had invalidated a Nuclear Regulatory Commission rule on the disposition of nuclear wastes for procedural insufficiencies -- namely the failure to allow intervenors discovery or cross-examination -- the Court characterized the lower court's approach as "Monday morning quarterbacking" and said that the APA's legislative history left little doubt "that Congress intended that the discretion of the *agencies* and not that of the courts be exercised in determining when extra procedural devices should be employed."[97]

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[93] *See National Small Shipments Traffic Conf. v. ICC*, 725 F.2d 1442, 1446 (D.C. Cir. 1984); Note, *Violations by Agencies of Their Own Regulations*, 87 Harv. L. Rev. 529 (1974).

[94] His approach was that courts should not "scrutinize the technical merits of each decision" but should "establish a decision-making process which assures a reasoned decision." *International Harvester v. Ruckelshaus*, 478 F.2d 615, 652 (D.C. Cir. 1973) (Bazelon J., concurring). Some of Judge Bazelon's colleagues on the court disagreed. *See* Wright, *The Courts and the Rulemaking Process: The Limits of Judicial Review*, 59 Cornell L. Rev. 375 (1974).

[95] 435 U.S. 519 (1978).

[96] *Natural Resources Defense Council, Inc. v. NRC*, 547 F.2d 633 (D.C. Cir. 1976)(J. Bazelon).

The Supreme Court stated that if agencies were forced to operate under the "vague injunction" to adopt those procedures "perfectly tailored to reach what the court perceives to be the 'best' or 'correct' result, judicial review would be totally unpredictable" and agencies would be encouraged or almost compelled to "adopt full adjudicatory procedures in every instance"[98] and "all the inherent advantages of informal rulemaking would be totally lost."[99] Finally, the Supreme Court said that reviewing courts are to judge the adequacy of the record in informal rulemaking not by the type of procedural devices employed, but rather by determining whether the agency has followed the procedural requirements of the APA and other relevant statutes.[100]

The reaction to *Vermont Yankee* among commentators was mixed, and opinion on the potential impact of the decision on judicial review of rulemaking varied widely.[101] However, in the years following, both the federal courts of appeals and the district courts have consistently followed *Vermont Yankee's* proscription against judicial remands based on agency failure to follow procedures not mandated by the APA.[102]

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[97] 435 U.S. at 545-47.

[98] *Id.* at 546.

[99] *Id.* at 547.

[100] *Id.*

[101] *See, e.g.*, Breyer, *Vermont Yankee and the Courts' Role in the Nuclear Energy Controversy*, 91 Harv. L. Rev. 1833 (1978); Davis, *Administrative Common Law and the Vermont Yankee*

It is important to note, however, that the *Vermont Yankee* decision has not been interpreted so broadly as to displace the case law that had developed with regard to the adequacy of notice, the opportunity to comment, and, most significantly, the adequacy of the agency's statement of basis and purpose under section 553 of the APA. Indeed, in *Vermont Yankee*, the Supreme Court cited with approval an earlier District of Columbia Circuit decision for the proposition that "[public] comments must be significant enough to step over a threshold requirement of materiality before any lack of agency response or consideration becomes of concern."[103]

Also bearing on the reach of *Vermont Yankee* is the Supreme Court's 1982 *State Farm* opinion,[104] which reversed NHTSA's rescission of a rule requiring passive restraints in cars. There, the Court reaffirmed a reviewing court's obligation under *Citizens to Preserve Overton Park v. Volpe* to determine if

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Opinion, 1980 Utah L. Rev. 3; Scalia, *Vermont Yankee: The APA, The D.C. Circuit, And The Supreme Court*, 1978 Sup. Ct. Rev. 345; Stewart, *Vermont Yankee and the Evolution of Administrative Procedure*, 91 Harv. L. Rev. 1805 (1978); Byse, *Vermont Yankee and the Evolution of Administrative Procedure: A Somewhat Different View*, 91 Harv. L. Rev. 1823 (1978).

[102] The court opinions are collected in Neely, *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.: Response and Reaction on the Federal Judiciary*, 14 U. Balt. L. Rev. 256 (1985).

[103] 435 U.S. at 553 (citing *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973)).

[104] *Motor Vehicles Mfrs. Ass'n v. State Farm Mutual Auto. Insur. Co.*, 463 U.S. 29 (1983). *See* discussion *supra*, subs. (2).

an agency decision is "based on a consideration of the relevant factors and whether there has been a clear error of judgment."[105] The Court found the agency's rule rescission to be arbitrary and capricious because the rulemaking record failed to present evidence or a rationale for not considering an "airbags only" rule.[106] In so doing, the Court also disposed of petitioners' argument that *Vermont Yankee* foreclosed placing such an additional procedural burden on the agency, stating: "We do not require today any specific procedures which NHTSA must follow."[107]

Considering the needs of reviewing courts charged under *Overton Park* with conducting "a thorough, probing, in-depth review"[108] of agency action based on the administrative record, it is unlikely that *Vermont Yankee* will be read to overturn the pre-*Vermont Yankee* judicial decisions interpreting section 553's notice, comment, and statement of basis and purpose requirements. On the other hand, the Supreme Court decision has largely halted reviewing court imposition of procedures beyond those in the APA.[109]

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[105] *Id.* at 43.

[106] *Id.* at 50.

[107] *Id.* at 50-51.

[108] *Citizens to Preserve Overton Park, Inc. v. Volpe*, *supra* n. 9, 401 U.S. at 415.

[109] *Vermont Yankee*, for example, has been cited by courts that have rejected the argument that notice-and-comment procedure is required for interpretive rules that have a "substantial impact" on the public, *see* Part II, Ch. 1(D)(2)(a). This conclusion has been criticized by Professor Kenneth C. Davis, *see* 2 K. Davis, Administrative Law Treatise §§ 7:17-7:19 (2d ed. 1979).

6. APA: Section 706(2)(E): "unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute"

The "substantial evidence" test is ordinarily applicable only to those adjudications or rulemakings (*i.e.*, formal rulemaking) conducted according to the trial-type procedures spelled out in sections 556 and 557 of the APA.[110] It typically has not been used in judicial review of informal rulemaking, which is subject to the arbitrary or capricious standard of review.

However, in the late 1960s and 1970s, Congress began to insert a substantial evidence test into some specific informal rulemaking statutes. The combination of informal rulemaking procedures with procedural elements associated with the adjudicatory process, in statutes such as the Occupational Safety and Health Act of 1970 and the Magnuson-Moss FTC Improvement Act of 1975, caused such statutes to be referred to as "hybrid" rulemaking statutes.[111] Congress' use of the substantial evidence test for review of rulemaking reflected its view that the more stringent test afforded the courts more leeway to monitor agency actions in implementing the new regulatory programs.

The linking of the substantial evidence test with proceedings involving "legislative" or "policy" types of judgments by agencies involved in informal rulemaking was thought by some to be anomalous, because as Judge McGowan stated in

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[110] Formal rulemaking requirements are discussed *supra*, Part II, Ch. 1(B).

[111] *See* discussion *supra*, Part I(C); Part III, Ch. 4(B)(2).

Industrial Union Department v. Hodgson,[112] decisions in informal rulemaking are typically not based on factual findings but rather on a "prediction based on pure legislative judgment."[113] The court, nevertheless, sought to give meaning to the substantial evidence test in that case, which involved an OSHA regulation. The court concluded that in reviewing informal rulemaking decisions under the substantial evidence test, the court's "paramount objective is to see whether the agency, given an essentially legislative task to perform, has carried it out in a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future."[114]

While Congress' occasional application of the substantial evidence test to informal rulemaking may have been intended to increase the scope of judicial review, it is by no means clear that the use of the test has brought about any significant changes in review under those statutes. This is consistent with the view that in court review of informal rulemaking, the substantial evidence and arbitrary or capricious tests have tended to converge.[115]

The Administrative Conference addressed the issue of the standard of judicial review of informal rulemaking in 1981, partly in response to Congressional interest in amending the scope of review. Recommendation No. 81-2, responding to the so-called Bumpers Amendment,[116] recommended that Section 706 of the APA be amended to provide that in applying the arbitrary or capricious test to rules promulgated under 5 U.S.C. § 553, "the court shall consider whether there is substantial support in the rulemaking file, viewed as a whole, for the asserted or necessary factual basis for the rule."[117]

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[112] 499 F.2d 467 (D.C. Cir. 1974).

[113] *Id.* at 474.

[114] *Id.* at 475 (citing *Automotive Parts & Accessories Ass'n v. Boyd*, 407 F.2d 330, 336 (1968).)

[115] See discussion *supra*, subs. (2).

7. *APA: Section 706(2)(F): "unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court"*

This clause covers the possibility that a reviewing court might determine the validity of agency action after holding a trial of its own on the factual issues involved in the proceeding. It applies in certain narrow categories of proceedings, such as civil rights cases under Title VII. Otherwise, according to *Camp v. Pitts*,[118] *de novo* review is appropriate only where there are inadequate fact-finding procedures in an adjudicatory proceeding, or where judicial proceedings are brought to enforce certain administrative actions.[119] Thus, this clause generally has no application to judicial review of informal rulemaking.

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[116] *See* n. 54, *supra*.

[117] "Current Versions of the Bumpers Amendment," 1981 ACUS Recommendation & Reports 7,¶ 3. The Administrative Law Section of the American Bar Association made a similar recommendation, *see* A Restatement of Scope of Review Doctrine, February 8, 1986, by the Section on Administrative Law of the ABA, *reprinted in* 38 Admin. L. Rev. 235 (1986). A section report of the Restatement by Professor Ronald M. Levin, Chair, Judicial Review Committee, is reprinted in 38 Admin. L. Rev. at 239.

In a 1974 Recommendation, "Preenforcement Judicial Review of Rules of General Applicability," 1 C.F.R. § 305.74-4, the Conference recommended that where statutes establish a substantial evidence standard for review of informal rulemaking, that standard should be construed as establishing a standard of review comparable to the arbitrary or capricious standard "unless a contrary intent clearly appears." *Id.*, ¶ 4. The Conference also recommended that in determining factual questions on review, a court should decide "whether the agency's conclusions concerning the significance of factual information can be said to be rationally supported." *Id.*, ¶ 3.

[118] 411 U.S. 138 (1973).

B. Record on Review

Rule 17 of the Federal Rules of Appellate Procedure states that when review of a regulation is sought in a court of appeals, "[t]he agency shall file the record with the clerk of the court . . . within 40 days after service . . . of the petition for review."[120] But nowhere in these rules is the composition of this record addressed. Various views on what the record in informal rulemaking proceedings should contain, and the Recommendation of the Administrative Conference of the United States on the subject, have been discussed above.[121] While the Conference's Recommendation would allow the agency to "proffer" documents in the record in addition to those it considered in the rulemaking, courts may be expected usually to require an agency to defend its rule in court on the record assembled during the course of the rulemaking proceeding. A contrary approach would seem to contravene the rule against *post hoc* rationalizations.[122]

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[119] *See e.g., McGlory v. United States*, 763 F.2d 309 (7th Cir. 1985).

[120] This time may be extended by motion, *see* Fed. R. App. P. 26(b).

[121] *See* Recommendation No. 74-4, *supra* n. 117, and discussion, *supra*, Part III, Ch. 5(B)(3). *See generally* Part III, Ch. 5.

[122] *See Motor Vehicles Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, *supra* n.23, at 50.

The Scope of Judicial Review

As discussed above,[123] records in rulemaking proceedings are sometimes quite unwieldy and courts may have little patience with unmanageable, unreadable records. Clearly an agency can help its cause by preparing a well-managed, orderly record. Under Rule 17(b) of the Federal Rules of Appellate Procedure, agencies may file the actual physical record with the court of appeals. However, this is generally discouraged.[124] More commonly used methods involve the filing of a certified list of all materials, or a stipulation approach by which the parties agree that designated portions of the record be filed. Under Rule 31(a), Federal Rules of Appellate Procedure, the petitioner must file its opening brief within 40 days of the filing of the record.[125]

The "appendix" is the term used for the separate volume or volumes containing those reproduced portions of the record submitted to the reviewing court. It renders the record more manageable for the judges, though the court may, of course, request any item from the whole record. For example in *Natural Resources Defense Council Inc. v. SEC*,[126] a record exceeding 10,000 pages was boiled down to a joint appendix of 877 pages. Rule 30 of the Federal Rules of Appellate Procedure spells out the procedure for reaching an agreement on the preparation of a joint appendix. Such procedure generally involves either stipulations or cross-designations by both parties.

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[123] *See* discussion *supra*, Part III, Ch. 5(B)(3).
[124] *See* Fed. R. App. P. 17(b).
[125] Fed. R. App. P. 31(a).
[126] 606 F.2d 1031, 1052 n. 28 (D.C. Cir. 1979).

PART FOUR: JUDICIAL REVIEW OF AGENCY RULEMAKING

CHAPTER 3

JUDICIAL REVIEW OF AGENCY FAILURE TO ACT

A. General Principles

Judicial review in the rulemaking area traditionally has been associated with challenges to administrative agency *actions*, *i.e.*, challenges to rules promulgated by the agency. The Administrative Procedure Act's judicial review provisions, however, are not so limited. Under section 706(1), a reviewing court may "compel agency action unlawfully withheld or unreasonably delayed." In addition, section 555(b) of the APA provides that "within a reasonable time, each agency shall proceed to conclude a matter presented to it."[1] Relying particularly on these provisions, courts of appeals have, on occasion, compelled agencies to initiate rulemaking proceedings[2] or to complete rulemaking "unreasonably delayed."[3]

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[1] 5 U.S.C. §§ 706(1), 555(b). Other provisions of the APA, notably 5 U.S.C. § 701(a)(2), have been cited as making review of agency inaction unreviewable. § 701(a)(2) exempts from APA review provisions "agency inaction committed to agency discretion by law."

[2] *See Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983), discussed *infra*, subs. (B)(1).

[3] *Telecommunications Research & Action Center v. FCC (TRAC)*, 750 F.2d 70 (D.C. Cir. 1984), discussed *infra*, subs. (B)(2). The courts also reviewed agency action in terminating

Review of Agency Inaction

The rationale for judicial review of agency failure to act has been described as follows: "Statutes designed to protect regulatory beneficiaries would be undone if agency implementation and enforcement were inadequate or nonexistent. Responding to this possibility, courts have relaxed traditional principles of standing, ripeness and prosecutorial discretion in order to permit review of agency inaction or of action that is assertedly inadequate."[4] At the same time, courts have recognized that they are generally not equipped to make the comparative judgments necessary to determine priorities for allocating scarce agency resources in the face of the many competing demands for government regulation and other essential agency activity.[5] As a consequence, courts have traditionally applied a highly deferential standard of review in reviewing cases of agency inaction.[6]

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rulemaking proceedings without issuing a standard. *See NRDC v. SEC*, 606 F.2d 1031 (D.C. Cir. 1979). See discussion *infra*, subs. (B)(3).

[4] Stewart & Sunstein, *Public Programs and Private Rights*, 95 Harv. L. Rev. 1193, 1205 (1982). Professors Stewart and Sunstein were addressing themselves more specifically to agency failure to enforce, *e.g., Dunlop v. Bachowski*, 421 U.S. 560 (1975), but the "initiation rights" which they discuss also apply to the rulemaking context; among other cases, they cite *NRDC v. SEC, supra* n. 3, a rulemaking case. *See also* Sunstein, *Reviewing Agency Inaction After Heckler v. Chaney*, 52 U. Chi. L. Rev. 653 (1985), particularly at 680-82 ("Failure to Initiate Rulemaking"). The issues of ripeness and finality in the context of agency rulemaking inaction are discussed *supra*, Part IV, Ch. 1(E).

[5] *See, e.g., National Congress of Hispanic American Citizens v. Marshall*, 626 F.2d 882 (D.C. Cir. 1979) (OSHA's refusal to issue field sanitation standard); *WWHT, Inc. v. FCC*, 656 F.2d 807 (D.C. Cir. 1981).

[6] *Id.* *See also Western Fuels-Illinois Inc. v. ICC*, 878 F.2d 1025, 1027 (7th Cir. 1989)("An agency decision not to institute rulemaking should be overturned only in the rarest and most compelling circumstances.")

Part IV: Judicial Review of Agency Failure to Act

The 1985 Supreme Court decision in *Heckler v. Chaney*[7] had a major influence on court review of agency inaction generally. The Court held that the Food and Drug Administration's decision not to initiate an enforcement action was presumptively unreviewable,[8] relying particularly on the following four considerations:

> 1. In setting enforcement priorities, agencies must evaluate a wide range of factors, which are particularly within their expertise; these factors include resources, likely success of the action, how the requested action "fits the agency's overall policies," and whether the agency has "enough resources to undertake the action at all."[9]
>
> 2. Refusal to take enforcement action generally does not involve the "exercise of [an agency's] *coercive* power over an individual's liberty or property rights";[10]
>
> 3. Since the agency has not taken a specific action, there is no "focus for judicial review."[11]
>
> 4. Agency refusal to take enforcement action shares some of the characteristics of a prosecutor's decision

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[7] 470 U.S. 821 (1985).

[8] The Court distinguished *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402 (1971), discussed *supra*, Part IV, Ch. 1(A), holding that *Overton Park's* presumption of reviewability was inapplicable where an agency refuses to take enforcement action. 470 U.S. at 831.

[9] 470 U.S. at 831-32.

[10] *Id.* at 832.

[11] *Id.* The court said that since the agency "must have exercised its power in some manner," agency *action* can "at

> not to indict, which has traditionally been held to be unreviewable.[12]

The Supreme Court expressly noted in *Chaney* that it was not deciding the question of "agency discretion not to invoke rulemaking proceedings."[13]

Although several of the considerations relied on by the Court for not exercising review in the enforcement context would arguably justify a court's refusal in ordinary circumstances to review agency rulemaking inaction, courts of appeals have, since *Chaney*, considered claims of agency inaction in rulemaking on the merits, either distinguishing *Chaney* or not referring to the Supreme Court decision at all.[14] However, where courts have found agency rulemaking inaction reviewable, they have continued to defer to agency decisions on the appropriate use of resources and determination of priorities.[15]

B. Types of Agency Inaction

Judicial review of agency inaction has generally arisen in one of three contexts: (1) agency failure to initiate rulemaking;

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least" be reviewed to determine if the agency exceeded its statutory powers. *Id.*

[12] *Id.*

[13] *Id.* at 825 n.2. The Court also distinguished situations where the agency refused to institute proceedings "based solely on the belief that it lacks jurisdiction" or where the agency adopts a "general policy" that is 'so extreme as to amount to an abdication of its statutory responsibilities." *Id.* at 833 n.4.

[14] These cases are discussed *infra*, subs. (B). *See* Levin, *Understanding Unreviewability in Administrative Law*, 74 Minn. L. Rev. 689, 762-773 (1990).

[15] *Id.*

(2) agency delay in an ongoing rulemaking proceeding; and (3) agency termination of a rulemaking without issuing a rule or issuing a very narrow rule.

1. *Failure to Initiate a Rulemaking*

In a notable pre-*Heckler v. Chaney* case, *Public Citizen Health Research Group v. Auchter*,[16] plaintiffs had filed a petition for rulemaking asking the Occupational Safety and Health Administration to issue a rule governing ethylene oxide. The District of Columbia Circuit in 1983, concluding that ethylene oxide was a carcinogen, that employees were exposed to "a significant risk of grave danger" from the toxic chemical, that OSHA delay in beginning a rulemaking proceeding amounted to "the least responsive course short of inaction" and that initiation of rulemaking would not disrupt other agency rulemakings of "higher or competing priority," found that OSHA was not concluding its regulatory action for ethylene oxide "within a reasonable time,"[17] as required by the APA.[18] Stressing the "documented risk to workers' lives and the children they may conceive,"[19] the court ordered OSHA to publish a proposal on ethylene oxide within 30 days, and stated that it expected the rulemaking to be concluded within a year.[20]

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[16] 702 F.2d 1150 (D.C. Cir. 1983).

[17] *Id.* at. 1157-58.

[18] *Id.* The court relied on the provisions in the OSHA Act requiring the agency to "give due regard to the urgency of the need" in determining standards priorities, 29 U.S.C. §§ 655(b), 706(1).

[19] 702 F.2d at 1158.

[20] *Id.* at 1154, 1158-59. The court refused to dictate a date for the issuance of the final rule. The district court had earlier ordered OSHA to issue an emergency temporary standard,

Review of Agency Inaction

American Horse Protection Association, Inc. v. Lyng[21] is a case involving agency refusal to initiate rulemaking arising after *Chaney*. In this case, plaintiff claimed that a Department of Agriculture (DOA) regulation against "soring"[22] had become outdated and should be revised in a new rulemaking.[23] The court addressed the reviewability of a refusal to institute rulemaking, saying that the issue has been a "source of some uncertainty" since *Chaney*.[24] While conceding that *Chaney's* reasoning applies "to some extent" to rulemaking, the court held it did not bar review in this case.[25] The court noted that the first two *Chaney* factors favoring nonreview -- agency expertise and non-exercise of "coercive" power -- are "likely to be involved in an agency's refusal to institute a rulemaking."[26] The parallel to prosecutorial decisions not to indict, however,

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which can become effective without rulemaking procedures. *Public Citizen Health Research Group v. Auchter*, 554 F. Supp. 242 (D.D.C. 1983). The court of appeals reversed the district court, emphasizing its reluctance to "*compel* the Assistant Secretary to grant extraordinary relief." 702 F.2d at 1157. A final ethylene oxide standard was ultimately issued by OSHA and upheld by the District of Columbia Circuit, *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986); *Public Citizen Health Research Group v. Brock*, 823 F.2d 626 (D.C. Cir. 1987).

In other OSHA cases, courts of appeals have indicated reluctance to compel emergency measures. *E.g., In Re International Chemical Workers Union*, 830 F.2d 369 (D.C. Cir. 1987).

[21] 812 F.2d 1 (D.C. Cir. 1987).

[22] "Soring" is a practice of deliberately injuring horses to improve their performance in public shows. The Horse Protection Act, 15 U.S.C. §§ 1821-24, prohibits soring, and the Department of Agriculture is authorized to issue regulations to implement these prohibitions. 15 U.S.C. § 1528.

[23] The plaintiff relied on a study prepared by a school of veterinary medicine showing the harmful effects of various training devices on horses. *Id.* at 2-3.

[24] *Id.* at 3.

[25] *Id.* at 4.

[26] *Id.*

traditionally within exclusive executive prerogative, was not applicable to rulemaking.[27] In contrast to prosecutorial decisions, which are frequent and based "mainly on close consideration of the facts of the case at hand, rather than on legal analysis," refusals to institute rulemaking are "likely to be relatively infrequent" and to turn on issues of law.[28] The court also pointed out that an agency's denial of a petition for rulemaking provides "a focus for judicial review" because of the APA's requirement of a public explanation for the denial.[29]

The court went on to apply the "arbitrary and capricious" test to the agency's refusal to initiate a new rulemaking, but noted that such "tag line" "encompasses a range of levels of deference to the agency," and reiterated the District of Columbia Circuit's oft-stated position that an agency's refusal to institute rulemaking "is at the high end of the [deference] range."[30] At the same time, the court held that refusal to initiate rulemaking "sets off a special alert" when a request for rulemaking is made on the basis of a "radical change in [the rule's] factual premises."[31] The court, stressing the cruel and inhumane nature of soring and the statute's goals, ultimately concluded that DOA had not presented a "reasoned explanation" of its failure to grant the rulemaking petition.[32] Nevertheless, the court did not order the DOA to initiate rulemaking, an order appropriate "only in the rarest and most compelling of circumstances,"[33] but remanded to the agency for a "reasonable opportunity to explain its decision or to institute a new rulemaking."[34]

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[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *Id.* at 4-5.

[31] *Id.* at 5. *Public Citizen Health Research Group v. Auchter, supra* n. 2, was this type of case, since new scientific data developed since the original rule showed the carcinogenicity of the chemical.

[32] *Id.* at 7.

In *National Customs Brokers & Forwarders Association v. Federal Maritime Comm'n*,[35] the District of Columbia Circuit applied the same deferential standard to a denial of request for rulemaking, this time in the context of economic regulation. Distinguishing such regulation from cases involving grave health and safety violations, the court deferred to the agency denial of the petition.[36]

2. *Delay in a Rulemaking Proceeding*

A second area where agency inaction has led to requests for judicial review is where an agency is accused of "unreasonable delay." There is some overlap with cases involving an agency's failure to initiate a rulemaking,[37] but a number of cases involve situations where the agency had begun a proceeding, which then extended over a period of years.

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[33] Citing *WWHT, Inc. v. FCC*, 656 F.2d 807, 818 (D.C. Cir. 1981).

[34] 812 F.2d at 7-8. The agency on remand again denied the petition for rulemaking. This action was challenged in *American Horse Protection Ass'n v. Lyng*, 681 F. Supp. 949 (D.D.C. 1988), where the court ordered the agency to initiate a rulemaking.

[35] 883 F.2d 93 (D.C. Cir. 1989).

[36] *Id.* at 103. *See also Western Fuels -- Illinois, Inc v. ICC*, *supra* n. 6, 878 F.2d at 1027, 1030 (noting "heavy burden" to show that rulemaking should be ordered, in case involving rail regulation).

[37] *See, e.g., Public Citizen Health Research Group v. Auchter*, *supra* n. 2.

Cases involving allegations of agency inaction inherently raise ripeness and finality issues,[38] since the agency's failure to take final action is what the case is about. Despite this, courts have looked for ways to address the issue of agency delay. In *Public Citizen Health Research Group v. Food and Drug Administration*,[39] the District of Columbia Circuit, although unwilling to review the substantive merits of the case, which involved a challenge to the FDA's failure to require certain health warnings on aspirin bottles, remanded to the District Court for a determination whether FDA had "unreasonably delayed" its resolution of the issue within the meaning of section 706(1) of the APA.[40] Noting that agency action must take into account statutory concerns for health and safety, the court of appeals said that "[i]f the [district] court finds unreasonable delay, it must fashion an appropriate remedy, which may include ordering rulemaking to begin immediately and proceed expeditiously, and ordering periodic reports to the court concerning the pace of rulemaking."[41]

In *Telecommunications Research & Action Center v. FCC (TRAC)*,[42] the District of Columbia Circuit set down certain factors to be considered in assessing claims of agency delay.

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[38] *See* discussion *supra*, Part IV, Ch. 1(E).

[39] 740 F.2d 21 (D.C. Cir. 1984). This case is also discussed *supra*, Part IV, Ch. 1(E).

[40] *Id.* at 34.

[41] *Id.* at 35. The court stressed that agency inaction or delay may be "tantamount to denial" of a petition for rulemaking and asserted: "In deciding whether the pace of decision is unreasonably delayed, the court should consider the nature and extent of the interests prejudiced by delay, the agency justification for the place of decision, and the context of the statutory scheme out of which the dispute arises." *Id.*

[42] *Supra* n. 3.

Although this case involved an adjudication rather than rulemaking, the court cited several rulemaking cases in distilling its "hexagonal contours of a standard" for determining whether there has been unreasonable delay.[43] The factors are:

> 1. The time that an agency may take to decide should be governed by a "rule of reason";
>
> 2. A statutory provision containing a timetable or similar "indication of speed" may "supply content for this rule of reason";
>
> 3. Delays are "less tolerable" where human health and welfare are at stake;
>
> 4. Consideration should be given to the effect of an order expediting action on "activities of a higher or competing priority";
>
> 5. The interests prejudiced by the delay should be considered;
>
> 6. No finding of "impropriety" by the agency is necessary as a basis for finding "unreasonable delay."[44]

In *TRAC*, the court did not issue the writ of mandamus sought by plaintiffs, in light of the FCC's assurance that it was "moving expeditiously" on the claims;[45] however, because of the FCC's prior failure to meet its own deadlines, the court, as it often has done, retained jurisdiction over the proceeding until final agency disposition.[46]

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[43] Among the cases cited are *Public Citizen Health Research Group v. Auchter, supra* n. 2, and *Public Citizen Health Research Group v. FDA, supra* n. 39.

[44] 750 F.2d at 80.

[45] *Id.* The courts have frequently accepted agency schedules, if found reasonable, for completion of rulemaking proceedings. *See, e.g., Oil, Chemical & Atomic Workers Int'l Union v. Zegeer*, 768 F.2d 1480, 1488 (D.C. Cir. 1985) ("[w]e are satisfied that MSHA [Mine Safety and Health Administration] is now proceeding toward completion of its rulemaking within a reasonable time.").

While these cases demonstrate that the courts of appeals are prepared to review agency inaction even after *Chaney*, the courts have generally strongly deferred to agencies' judgments on their priorities. An example is *Sierra Club v. Thomas*,[47] where the District of Columbia Circuit held that EPA's delay in concluding rulemaking was not unreasonable, stating: "Because 'a court is in general ill-suited to review the order in which an agency conducts its business,' we are properly hesitant to upset an agency's priorities by ordering it to expedite one specific action, and thus to give it precedence over others."[48] Similarly, the same court refused, in *United*

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[46] 750 F.2d at 81. *See, e.g.*, *International Union UAW v. Donovan*, 756 F.2d 162, 165 (D.C. Cir. 1985) (OSHA formaldehyde standard). In *In Re Center for Auto Safety*, 793 F.2d 1346 (D.C. Cir. 1986), also a post-*Chaney* case, the court considered a challenge to NHTSA's failure on several occasions to meet statutory deadlines for promulgating fuel economy standards for light trucks. The court found the agency delays "unreasonable," distinguishing the *Zegeer* case, *supra* n. 45, on the ground that in the NHTSA case it was dealing with "statutorily mandated annual rulemakings beset with repeated delay." *Id.* at 1354 & n.55. Although the statute contained a timetable for action, since the agency had issued 1987 and 1988 standards and "made some progress" in 1989, the court decided, while retaining jurisdiction, "to stay its hand for the time being." *Id.* at 1354.

[47] 828 F.2d 783 (D.C. Cir. 1987).

[48] *Id.* at 797 (quoting *EDF v. Hardin*, 428 F.2d 1093, 1099 (D.C. Cir. 1970)). In reaching this conclusion, the court relied on the facts that the statute gave no special priority to completion of this rulemaking nor did the statute "instruct" EPA to regulate this subject matter; since EPA's entire docket consists of health regulatory issues, any acceleration in this proceeding would come at the expense of action elsewhere. *Id.* at 797-98. The court also noted that the agency had already proceeded through the comment period in the rulemaking, and because the proceeding involves "complex scientific, technological and policy questions, [it] must be afforded the

Steelworkers of America v. Rubber Manufacturing Ass'n,[49] to order OSHA to expedite its rulemaking on benzene, saying that "judicial imposition of any overly hasty timetable at this stage would ill serve the public interest," since the rule and its rationale "must be constructed carefully and thoroughly if the agency's action is to pass judicial scrutiny . . . ."[50]

3. *Termination of Rulemaking*

Termination of rulemaking without issuing a rule is also a type of agency inaction. In this situation, however, the agency has generally already expended resources, and compiled a substantial record, making judicial review easier. In *Williams National Gas Co. v. FERC*,[51] the District of Columbia Circuit reviewed a FERC order terminating an ongoing rulemaking under the Natural Gas Policy Act.[52] The court, noting that the agency had issued a lengthy document expressing its tentative view that the regulation should be changed and received comments on the issue, concluded that there was a sufficient evidentiary basis for determining whether the agency decision was arbitrary or capricious.[53] Relying on *NRDC v. SEC*,[54] which "drew a clear, distinction between an agency's refusal to undertake a rulemaking (reviewable, if at all, under an exceedingly narrow standard) and its decision to terminate a

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amount of time necessary to analyze such questions" so as not to risk judicial invalidation. *Id.* at 798.

[49] 783 F.2d 1117 (D.C. Cir. 1986).

[50] *Id.* at 1120. The court characterized the request for a mandatory, accelerated, timetable as an "invitation to 'punish' OSHA." *Id.*

[51] 872 F.2d 438 (D.C. Cir. 1989).

[52] 15 U.S.C. § 3301 *et seq.*

[53] 872 F.2d at 443.

[54] *Supra* n. 3, 606 F.2d at 1045-47.

docket after a substantial record has been compiled," the court looked in detail at the agency's rationale in determining that FERC had not articulated a reasoned explanation for its decision. The court remanded to the agency for further consideration.[55]

The same policy consideration would apply to court review where the agency after rulemaking issues a rule with exemption for significant groups. Thus, in *United Steelworkers of America v. Auchter*,[56] the Third Circuit remanded OSHA's hazard communication rule for reconsideration of its decision not to apply the rule to non-manufacturing sectors of business.[57] The court rejected the agency's argument that its priority-setting authority barred review of its decision not to cover non-manufacturing industries, saying that since the rulemaking had been completed, the agency had failed to explain why coverage of nonmanufacturing in the final rule "would have seriously impeded the rulemaking process."[58]

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[55] The court did not require the agency to issue a rule; it noted that the agency "retains wide discretion on remand." *Id.* at 450. In *Farmworker Justice Fund v. Brock*, 811 F.2d 613 (D.C. Cir.), *vacated as moot*, 817 F.2d 890 (D.C. Cir. 1987), the court reviewed OSHA's decision to terminate a 14-year long rulemaking without issuing a rule. The court analyzed the *Chaney* case as not precluding judicial review where the "decision is based on factors that the court is competent to evaluate," or where the agency decision is contrary to law. *Id.* at 621-22. The court found that OSHA had based its decision not to issue a field sanitation standard for farmworkers on impermissible factors.

[56] 763 F.2d 728 (3d Cir. 1985).

[57] *Id.* at 739.

[58] *Id.* at 738. *See also United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1309-10 (D.C. Cir. 1980), *cert. denied*, 453 U.S. 913 (1981)(reviewing OSHA's exemption of construction industry from lead standard). The same principle was applied in *Colorado v. Department of Interior*, 880 F.2d 481, 485 (D.C. Cir. 1989). There, the agency was challenged for not

4. *Other Agency Inaction*

In a situation where the agency has failed to act in a timely fashion on the court's remand of a rule for reconsideration, the court had no difficulty in concluding that the agency's nonaction was reviewable. Thus, in *Public Citizen Health Research Group v. Brock*,[59] involving the OSHA ethylene oxide proceeding after remand,[60] the District of Columbia Circuit scolded the agency for its failure to act on the remand order by promptly initiating rulemaking on the short-term exposure issue.[61] It rejected a request to find the agency in contempt, however, finding that the agency schedule for completion of the rulemaking was reasonable, but warning that failure to meet that self-imposed schedule would constitute "unreasonable delay."[62]

C. Summary

In summary, despite the Supreme Court decision in *Heckler v. Chaney*,[63] the courts have reviewed agency failure to take rulemaking actions in a number of situations:

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issuing "more comprehensive" regulations; the court held that the case was different from a petition to compel action where the agency had not yet acted, since "final agency action" was involved.

[59] 823 F.2d 626 (D.C. Cir. 1987).

[60] The earlier stage of this proceeding is discussed *supra*, subs. (B)(1). The court remanded the rule to OSHA for its consideration of a short-term exposure limit for the chemical. 823 F.2d at 629.

[61] *Id.* at 628-29.

[62] *Id.* at 629. *See also United Steelworkers of America v. Pendergrass*, 819 F.2d 1263 (3d Cir. 1986) (court review of OSHA's failure to act on partial remand of hazard communication standard).

[63] 470 U.S. 821 (1985), discussed *supra*, subs. (A).

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1. The court will ordinarily be most deferential where the question is whether the agency should *initiate* a rulemaking proceeding.[64] Where the court decides to compel action, it will typically require only that the agency issue a *proposed* rule.[65]

2. Where the agency commences rulemaking but delays its completion, courts will evaluate a host of factors in deciding whether to compel action. These were summarized in the *TRAC* case.[66] Substantial deference will still be given to agency discretion in managing its priorities; however, circumstances may exist showing that the agency delay is "unreasonable."[67] In some cases, the court will not decide on a deadline, but will insist that the agency provide an appropriate timetable which the court will monitor.[68]

3. A case in which the agency has completed rulemaking but decided not to issue a rule or issued a "less comprehensive" rule than is being sought represents the opposite end of the review spectrum. In that situation, since resource considerations are less important and there is a public record for court

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[64] *See* subs. (B)(1), *supra*.

[65] *See* discussion of *Public Citizen Health Research Group v. Auchter*, *supra* n. 2, and *American Horse Protection Ass'n v. Lyng*, *supra* n. 21.

[66] *See* subs. (B)(2), *supra*.

[67] *Id.*

[68] *Oil, Chemical & Atomic Workers, Int'l v. Zegeer*, *supra* n. 45.

review, the court will review the agency failure to act in much the same way as it would agency action.[69]

4. Failure of an agency promptly to act on a remand from the court is likely to elicit a sharp rebuke and forceful response.[70]

Suits to compel agency rulemaking action often raise issues of finality, ripeness, and failure to exhaust,[71] and implicate also the question of the "record" of agency actions before the court.[72]

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[69] *See* subs. B(3)(C), *supra*.

[70] *See Public Citizen Health Research Group v. Brock*, *supra* 20.

[71] Discussed *supra*, Part IV, Ch. 1(E).

[72] Discussed *supra*, Part III, Ch. 5; Part IV, Ch. 2(B).

CONSULTANT'S AFTERWORD

Since 1983, when the original Administrative Conference Guide to Federal Agency Rulemaking was published, our federal government has undergone many changes, but, despite all of these changes, the legal landscape of rulemaking has remained much the same. The Administrative Procedure Act, now past its fortieth birthday, continues to hold center stage in the rulemaking drama. Quasi-legislative rules still form the backbone of most regulatory programs. The major players in rulemaking are the same, except that the Office of Management and Budget has assumed a more central role. In the early part of the decade, some commentators saw a "malaise" in rulemaking and feared for its future. In retrospect, these commentators were unduly pessimistic, having failed adequately to take into account the flexibility and innovative potentialities of this "great invention" of modern administrative government.

Looking at the next decade, several rulemaking issues are likely to loom large. Delays in completion of rulemaking proceedings and decisions on selection of rulemaking priorities continue to generate public concern and controversy. Congress' increased reliance on statutory deadlines for rulemaking action has not been a panacea, having led, at best, to mixed results. The role of the courts in ordering agencies to commence or complete rulemaking has increased and has been a significant factor in constraining agency inaction, but the ultimate extent of the court's role in providing affirmative rulemaking relief remains undefined.

To expedite rulemaking, administrative agencies have adopted new and improved procedures such as "generic" rulemaking. Regulatory negotiation, increasingly used by agencies, received an important boost through the recent enactment of the Negotiated Rulemaking Act. On the other hand, efforts by some agencies, in the interest of efficiency, to rely on exceptions to mandatory notice-and-comment requirements, have often been challenged and sometimes overruled by court decisions, which regrettably, have not always been reliable guides to the scope of APA exemptions.

Presidential and OMB review of major agency rules has elicited frequent objection, partly because it has caused operational delays, and partly on constitutional and statutory grounds. However, the courts so far have avoided interfering with Presidential control over rulemaking. Even the Supreme Court decision in *Dole v. United Steelworkers of America,*[1] which limited OMB review under the Paperwork Reduction Act, was based on narrow statutory grounds and not on constitutional principles.

The evolving relationship between the courts and administrative agencies has played a critical role in the rulemaking revolution of the past two decades. The Supreme Court spoke to the issue of court review of agency rules in 1984 when it decided the *State Farm* air-bag case[2] and the *Chevron* "bubble" case.[3] These decisions delivered somewhat mixed signals, however, with *State Farm* mandating a "hard look" at agency rules, and *Chevron* emphasizing deference to agency policymaking interpretations. Since 1984, much of the attention of the Supreme Court itself, as well as the courts of appeals, has been devoted to mapping out the meaning and application of these landmark decisions. Like the *Overton Park* decision[4] twenty years earlier, *State Farm* and *Chevron* are likely to continue to provide the framework for the seemingly never-ending dialogue on the shape of the partnership between courts and administrative agencies.

Several other developments in the study of rulemaking are worthy of special note. State administrative law and, in particular state rulemaking, has become the subject of considerable new interest.[5] This study has become important as the states have assumed an increased regulatory role, and the broad variety of state procedures has provided a constructive comparison to the more familiar mechanics of federal rulemaking. There have also been interchanges with foreign countries, including those in newly-democratized Eastern Europe, about their administrative law systems.[6]

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[1] 110 S. Ct. 929 (1990).

[2] *Motor Vehicles Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983).

[3] *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984).

[4] *Citizens to Protect Overton Park v. Volpe*, 401 U.S. 402 (1971).

[5] *See, e.g.*, Bonfield, *State Administrative Policy Formulation and the Choice of Lawmaking Methodology*, 42 Admin. L. Rev. 121 (1990).

Scholarly work, of course, continues unabated, as new approaches and fresh points of view are brought to the study of rulemaking. One important and relatively new area has been the examination of the political components of rulemaking, and here major work is being completed by scholars in the fields of political science and government as well as by legal scholars.[7] In-depth studies of particularly important and lengthy rulemaking proceedings and regulatory programs,[8] and of the challenges to administrative law posed by massive government programs, such as social security and welfare,[9] have been undertaken. A broad range of administrative law textbooks has been published, each containing extensive sections on rulemaking.[10] Finally, the Administrative Conference of the United States has continued its valuable work, and in recent years has made a number of recommendations and published supporting studies in the rulemaking area. Two of these recommendations, relating to venue of court review and regulatory negotiation, resulted in congressional legislation implementing the proposed reforms.

Benjamin W. Mintz

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[6] *See* Strauss, An Introduction to Administrative Justice in the United States (1989), part of a series entitled Administrative Justice in the Western Democracies, *id.* at 3.

[7] *See, e.g.*, McCubbins, Noll & Weingast, *Structure and Process, Politics and Policy: Administrative Arrangements and the Political Control of Agencies*, 75 Va. L. Rev. 431 (1989); West, Administrative Rulemaking: Politics and Process (1985).

[8] *See, e.g.*, Mashaw & Harfst, The Struggle for Auto Safety (1990).

[9] *E.g.*, Mashaw, Bureaucratic Justice -- Managing Social Security Disability Claims (1983).

[10] Among many others, see Bonfield & Asimow, State and Federal Administrative Law (1989); Cass & Diver, Administrative Law -- Cases and Materials (1987); Gellhorn, Byse, Strauss, Rakoff & Schotland, Administrative Law -- Cases and Comments (8th ed. 1987).

APPENDIX A

Selected Sections of the Administrative Procedure Act

5 U.S.C. (1988 ed.)

§ 551. Definitions

For the purpose of this subchapter—

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include—

(A) the Congress;

(B) the courts of the United States;

(C) the governments of the territories or possessions of the United States;

(D) the government of the District of Columbia;

or except as to the requirements of section 552 of this title—

(E) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them;

(F) courts martial and military commissions;

(G) military authority exercised in the field in time of war or in occupied territory; or

(H) functions conferred by sections 1738, 1739, 1743, and 1744 of title 12; chapter 2 of title 41; or sections 1622, 1884, 1891-1902, and former section 1641(b)(2), of title 50, appendix;

(2) "person" includes an individual, partnership, corporation, association, or public or private organization other than an agency;

(3) "party" includes a person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party, in an agency proceeding, and a person or agency admitted by an agency as a party for limited purposes;

(4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial

structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing;

(5) "rule making" means agency process for formulating, amending, or repealing a rule;

(6) "order" means the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing;

(7) "adjudication" means agency process for the formulation of an order;

(8) "license" includes the whole or a part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission;

(9) "licensing" includes agency process respecting the grant, renewal, denial, revocation, suspension, annulment, withdrawal, limitation, amendment, modification, or conditioning of a license;

(10) "sanction" includes the whole or a part of an agency—

(A) prohibition, requirement, limitation, or other condition affecting the freedom of a person;

(B) withholding of relief;

(C) imposition of penalty or fine;

(D) destruction, taking, seizure, or withholding of property;

(E) assessment of damages, reimbursement, restitution, compensation, costs, charges, or fees;

(F) requirement, revocation, or suspension of a license; or

(G) taking other compulsory or restrictive action;

(11) "relief" includes the whole or a part of an agency—

(A) grant of money, assistance, license, authority, exemption, exception, privilege, or remedy;

(B) recognition of a claim, right, immunity, privilege, exemption, or exception; or

(C) taking of other action on the application or petition of, and beneficial to, a person;

(12) "agency proceeding" means an agency process as defined by paragraphs (5), (7), and (9) of this section;

(13) "agency action" includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act; and

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(14) "ex parte communication" means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by this subchapter.

§ 552. Public information; agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public—

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

* * *

§ 553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

§ 554. Adjudications

(a) This section applies, according to the provisions thereof, in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing, except to the extent that there is involved—

(1) a matter subject to a subsequent trial of the law and the facts de novo in a court;

(2) the selection or tenure of an employee, except a[*] administrative law judge appointed under section 3105 of this title;

(3) proceedings in which decisions rest solely on inspections, tests, or elections;

(4) the conduct of military or foreign affairs functions;

(5) cases in which an agency is acting as an agent for a court; or

(6) the certification of worker representatives.

(b) Persons entitled to notice of an agency hearing shall be timely informed of—

(1) the time, place, and nature of the hearings;

(2) the legal authority and jurisdiction under which the hearing is to be held; and

(3) the matters of fact and law asserted.

When private persons are the moving parties, other parties to the proceeding shall give prompt notice of issues controverted in fact or law; and in other instances agencies may by rule require responsive pleading. In fixing the time and place for hearings, due regard shall be had for the convenience and necessity of the parties or their representatives.

(c) The agency shall give all interested parties opportunity for—

(1) the submission and consideration of facts, arguments, offers of settlement, or proposals of adjustment when time, the nature of the proceeding, and the public interest permit; and

(2) to the extent that the parties are unable so to determine a controversy by consent, hearing and decision on notice and in accordance with sections 556 and 557 of this title.

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[*] So in original.

(d) The employee who presides at the reception of evidence pursuant to section 556 of this title shall make the recommended decision or initial decision required by section 557 of this title, unless he becomes unavailable to the agency. Except to the extent required for the disposition of ex parte matters as authorized by law, such an employee may not—

(1) consult a person or party on a fact in issue, unless on notice and opportunity for all parties to participate; or

(2) be responsible to or subject to the supervision or direction of an employee or agent engaged in the performance of investigative or prosecuting functions for an agency.

An employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case may not, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review pursuant to section 557 of this title, except as witness or counsel in public proceedings. This subsection does not apply—

(A) in determining applications for initial licenses;

(B) to proceedings involving the validity or application of rates, facilities, or practices of public utilities or carriers; or

(C) to the agency or a member or members of the body comprising the agency.

(e) The agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty.

§ 555. Ancillary matters

(a) This section applies, according to the provisions thereof, except as otherwise provided by this subchapter.

(b) A person compelled to appear in person before an agency or representative thereof is entitled to be accompanied, represented, and advised by counsel or, if permitted by the agency, by other qualified representative. A party is entitled to appear in person or by or with counsel or other duly qualified representative in an agency proceeding. So far as the orderly conduct of public business permits, an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding, whether interlocutory, summary, or otherwise, or in connection with an agency function. With due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency shall proceed to conclude a matter presented to it. This subsection does not grant or deny a person who is not a lawyer the right to appear for or represent others before an agency or in an agency proceeding.

(c) Process, requirement of a report, inspection, or other investigative act or demand may not be issued, made, or enforced except as authorized by law. A person compelled to submit data or evidence is entitled to retain or, on payment of lawfully prescribed costs, procure a copy or transcript thereof, except that in a nonpublic investigatory proceeding the witness may for good cause be limited to inspection of the official transcript of his testimony.

(d) Agency subpenas authorized by law shall be issued to a party on request and, when required by rules of procedure, on a statement or showing of general relevance and reasonable scope of the evidence sought. On contest, the court shall sustain the subpena or similar process or demand to the extent that it is found to be in accordance with law. In a proceeding for enforcement, the court shall issue an order requiring the appearance of the witness or the production of the evidence or data within a reasonable time under penalty of punishment for contempt in case of contumacious failure to comply.

(e) Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceedings. Except in affirming a prior denial or when the denial is self-explanatory, the notice shall be accompanied by a brief statement of the grounds for denial.

§ 556. Hearings; presiding employees; powers and duties; burden of proof; evidence; record as basis of decision

(a) This section applies, according to the provisions thereof, to hearings required by section 553 or 554 of this title to be conducted in accordance with this section.

(b) There shall preside at the taking of evidence—

(1) the agency;

(2) one or more members of the body which comprises the agency; or

(3) one or more administrative law judges appointed under section 3105 of this title.

This subchapter does not supersede the conduct of specified classes of proceedings, in whole or in part, by or before boards or other employees specially provided for by or designated under statute. The functions of presiding employees and of employees participating in decisions in accordance with section 557 of this title shall be conducted in an impartial manner. A presiding or participating employee may at any time disqualify himself. On the filing in good faith of a timely and sufficient affidavit of personal bias or other disqualification of a presiding or participating employee, the agency shall determine the matter as a part of the record and decision in the case.

(c) Subject to published rules of the agency and within its powers, employees presiding at hearings may—

(1) administer oaths and affirmations;

(2) issue subpenas authorized by law;

(3) rule on offers of proof and receive relevant evidence;

(4) take depositions or have depositions taken when the ends of justice would be served;

(5) regulate the course of the hearing;

(6) hold conferences for the settlement or simplification of the issues by consent of the parties;

(7) dispose of procedural requests or similar matters;

(8) make or recommend decisions in accordance with section 557 of this title; and

(9) take other action authorized by agency rule consistent with this subchapter.

(d) Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof. Any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence. The agency may, to the extent consistent with the interests of justice and the policy of the underlying statutes administered by the agency, consider a violation of section 557(d) of this title sufficient grounds for a decision adverse to a party who has knowingly committed such violation or knowingly caused such violation to occur. A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. In rule making or determining claims for money or benefits or applications for initial licenses an agency may, when a party will not be prejudiced thereby, adopt procedures for the submission of all or part of the evidence in written form.

(e) The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision in accordance with section 557 of this title and, on payment of lawfully prescribed costs, shall be made available to the parties. When an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.

§ 557. Initial decisions; conclusiveness; review by agency; submissions by parties; contents of decisions; record

(a) This section applies, according to the provisions thereof, when a hearing is required to be conducted in accordance with section 556 of this title.

(b) When the agency did not preside at the reception of the evidence, the presiding employee or, in cases not subject to section 554(d) of this title, an employee qualified to preside at hearings pursuant to section 556 of this title, shall initially decide the case unless the agency requires, either in specific cases or by general rule, the entire record to be certified to it for decision. When the presiding employee makes an initial decision, that decision then becomes the decision of the agency without further proceedings unless there is an appeal to, or review on motion of, the agency within time provided by rule. On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule. When the agency makes the decision without having presided at the reception of the evidence, the presiding employee or an employee qualified to preside at hearings pursuant to section 556 of this title shall first recommend a decision, except that in rule making or determining applications for initial licenses—

(1) instead thereof the agency may issue a tentative decision or one of its responsible employees may recommend a decision; or

(2) this procedure may be omitted in a case in which the agency finds on the record that due and timely execution of its functions imperatively and unavoidably so requires.

(c) Before a recommended, initial, or tentative decision, or a decision on agency review of the decision of subordinate employees, the parties are entitled to a reasonable opportunity to submit for the consideration of the employees participating in the decisions—

(1) proposed findings and conclusions; or

(2) exceptions to the decisions or recommended decisions of subordinate employees or to tentative agency decisions; and

(3) supporting reasons for the exceptions or proposed findings or conclusions.

The record shall show the ruling on each finding, conclusion, or exception presented. All decisions, including initial, recommended, and tentative decisions, are a part of the record and shall include a statement of—

(A) findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law, or discretion presented on the record; and

(B) the appropriate rule, order, sanction, relief, or denial thereof.

(d)(1) In any agency proceeding which is subject to subsection (a) of this section, except to the extent required for the disposition of ex parte matters as authorized by law—

(A) no interested person outside the agency shall make or knowingly cause to be made to any member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of the proceeding, an ex parte communication relevant to the merits of the proceeding;

(B) no member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of the proceeding, shall make or knowingly cause to be made to any interested person outside the agency an ex parte communication relevant to the merits of the proceeding;

(C) a member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of such proceeding who receives, or who makes or knowingly causes to be made, a communication prohibited by this subsection shall place on the public record of the proceeding:

(i) all such written communications;

(ii) memoranda stating the substance of all such oral communications; and

(iii) all written responses, and memoranda stating the substance of all oral responses, to the materials described in clauses (i) and (ii) of this subparagraph;

(D) upon receipt of a communication knowingly made or knowingly caused to be made by a party in violation of this subsection, the agency, administrative law judge, or other employee presiding at the hearing may, to the extent consistent with the interests of justice and the policy of the underlying statutes, require the party to show cause why his claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected on account of such violation; and

(E) the prohibitions of this subsection shall apply beginning at such time as the agency may designate, but in no case shall they begin to apply later than the time at which a proceeding is noticed for hearing unless the person responsible for the communication has knowledge that it will be noticed, in which case the prohibitions shall apply beginning at the time of his acquisition of such knowledge.

(2) This subsection does not constitute authority to withhold information from Congress.

* * *

§ 701. Application; definitions

(a) This chapter applies, according to the provisions thereof, except to the extent that—

(1) statutes preclude judicial review; or

(2) agency action is committed to agency discretion by law.

(b) For the purpose of this chapter—

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include—

(A) the Congress;

(B) the courts of the United States;

(C) the governments of the territories or possessions of the United States;

(D) the government of the District of Columbia;

(E) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them;

(F) courts martial and military commissions;

(G) military authority exercised in the field in time of war or in occupied territory; or

(H) functions conferred by sections 1738, 1739, 1743, and 1744 of title 12; chapter 2 of title 41; or sections 1622, 1884, 1891-1902, and former section 1641(b)(2), of title 50, appendix; and

(2) "person", "rule", "order", "license", "sanction", "relief", and "agency action" have the meanings given them by section 551 of this title.

§ 702. Right of review

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: *Provided*, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

§ 703. Form and venue of proceeding

The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. If no special statutory review proceeding is applicable, the action for judicial review may be brought against the United States, the agency by its official title, or the appropriate officer. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.

§ 704. Actions reviewable

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsiderations, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

§ 705. Relief pending review

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

APPENDIX B

Executive Order No. 12,291
3 C.F.R. 127 (1981)

FEDERAL REGULATION

By the authority vested in me as President by the Constitution and laws of the United States of America, and in order to reduce the burdens of existing and future regulations, increase agency accountability for regulatory actions, provide for presidential oversight of the regulatory process, minimize duplication and conflict of regulations, and insure well-reasoned regulations, it is hereby ordered as follows:

Section 1. *Definitions.* For the purposes of this Order:

(a) "Regulation" or "rule" means an agency statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the procedure or practice requirements of an agency, but does not include:

(1) Administrative actions governed by the provisions of Sections 556 and 557 of Title 5 of the United States Code;

(2) Regulations issued with respect to a military or foreign affairs function of the United States; or

(3) Regulations related to agency organization, management or personnel.

(b) "Major rule" means any regulation that is likely to result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

(c) "Director" means the Director of the Office of Management and Budget.

(d) "Agency" means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), excluding those agencies specified in 44 U.S.C. 3502(10).

(e) "Task Force" means the Presidential Task Force on Regulatory Relief.

Sec. 2. *General Requirements.* In promulgating new regulations, reviewing existing regulations, and developing legislative proposals concerning regulation, all agencies, to the extent permitted by law, shall adhere to the following requirements:

(a) Administrative decisions shall be based on adequate information concerning the need for and consequences of proposed government action;

(b) Regulatory action shall not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society;

(c) Regulatory objectives shall be chosen to maximize the net benefits to society;

(d) Among alternative approaches to any given regulatory objective, the alternative involving the least net cost to society shall be chosen; and

(e) Agencies shall set regulatory priorities with the aim of maximizing the aggregate net benefits to society, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory actions contemplated for the future.

Sec. 3. *Regulatory Impact Analysis and Review.*

(a) In order to implement Section 2 of this Order, each agency shall, in connection with every major rule, prepare, and to the extent permitted by law consider, a Regulatory Impact Analysis. Such Analyses may be combined with any Regulatory Flexibility Analyses performed under 5 U.S.C. 603 and 604.

(b) Each agency shall initially determine whether a rule it intends to propose or to issue is a major rule, *provided that,* the Director, subject to the direction of the Task Force, shall have authority, in accordance with Sections 1(b) and 2 of this Order, to prescribe criteria for making such determinations, to order a rule to be treated as a major rule, and to require any set of related rules to be considered together as a major rule.

(c) Except as provided in Section 8 of this Order, agencies shall prepare Regulatory Impact Analyses of major rules and transmit them, along with all notices of proposed rulemaking and all final rules, to the Director as follows:

(1) If no notice of proposed rulemaking is to be published for a proposed major rule that is not an emergency rule, the agency shall prepare only a final Regulatory Impact Analysis, which shall be transmitted, along with the proposed rule, to the Director at least 60 days prior to the publication of the major rule as a final rule;

(2) With respect to all other major rules, the agency shall prepare a preliminary Regulatory Impact Analysis, which shall be transmitted, along with a notice of proposed rulemaking, to the Director at least 60 days prior to the publication of a notice of proposed rulemaking, and a final Regulatory Impact Analysis, which shall be transmitted along with the final rule at least 30 days prior to the publication of the major rule as a final rule;

(3) For all rules other than major rules, agencies shall submit to the Director, at least 10 days prior to publication, every notice of proposed rulemaking and final rule.

(d) To permit each proposed major rule to be analyzed in light of the requirements stated in Section 2 of this Order, each preliminary and final Regulatory Impact Analysis shall contain the following information:

(1) A description of the potential benefits of the rule, including any beneficial effects that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits;

(2) A description of the potential costs of the rule, including any adverse effects that cannot be quantified in monetary terms, and the identification of those likely to bear the costs;

(3) A determination of the potential net benefits of the rule, including an evaluation of effects that cannot be quantified in monetary terms;

(4) A description of alternative approaches that could substantially achieve the same regulatory goal at lower cost, together with an analysis of this potential benefit and costs and a brief explanation of the legal reasons why such alternatives, if proposed, could not be adopted; and

(5) Unless covered by the description required under paragraph (4) of this subsection, an explanation of any legal reasons why the rule cannot be based on the requirements set forth in Section 2 of this Order.

(e)(1) The Director, subject to the direction of the Task Force, which shall resolve any issues raised under this Order or ensure that they are presented to the President, is authorized to review any preliminary or final Regulatory Impact Analysis, notice of proposed rulemaking, or final rule based on the requirements of this Order.

(2) The Director shall be deemed to have concluded review unless the Director advises an agency to the contrary under subsection (f) of this Section:

(A) Within 60 days of a submission under subsection (c)(1) or a submission of a preliminary Regulatory Impact Analysis or notice of proposed rulemaking under subsection (c)(2);

(B) Within 30 days of the submission of a final Regulatory Impact Analysis and a final rule under subsection (c)(2); and

(C) Within 10 days of the submission of a notice of proposed rulemaking or final rule under subsection (c)(3).

(f)(1) Upon the request of the Director, an agency shall consult with the Director concerning the review of a preliminary Regulatory Impact Analysis or notice of proposed rulemaking under this Order, and shall, subject to Section 8(a)(2) of this Order, refrain from publishing its preliminary Regulatory Impact Analysis or notice of proposed rulemaking until such review is concluded.

(2) Upon receiving notice that the Director intends to submit views with respect to any final Regulatory Impact Analysis or final rule, the agency shall, subject to Section 8(a)(2) of this Order, refrain from publishing its final Regulatory Impact Analysis or final rule until the agency has responded to the Director's views, and incorporated those views and the agency's response in the rulemaking file.

(3) Nothing in this subsection shall be construed as displacing the agencies' responsibilities delegated by law.

(g) For every rule for which an agency publishes a notice of proposed rulemaking, the agency shall include in its notice:

(1) A brief statement setting forth the agency's initial determination whether the proposed rule is a major rule, together with the reasons underlying that determination; and

(2) For each proposed major rule, a brief summary of the agency's preliminary Regulatory Impact Analysis.

(h) Agencies shall make their preliminary and final Regulatory Impact Analyses available to the public.

(i) Agencies shall initiate reviews of currently effective rules in accordance with the purposes of this Order, and perform Regulatory Impact Analyses of currently effective major rules. The Director, subject to the direction of the Task Force, may designate currently effective rules for review in accordance with this Order, and establish schedules for reviews and Analyses under this Order.

Sec. 4. *Regulatory Review*. Before approving any final major rule, each agency shall:

(a) Make a determination that the regulation is clearly within the authority delegated by law and consistent with congressional intent, and include in the *Federal Register* at the time of promulgation a memorandum of law supporting that determination.

(b) Make a determination that the factual conclusions upon which the rule is based have substantial support in the agency record, viewed as a whole, with full attention to public comments in general and the comments of persons directly affected by the rule in particular.

Sec. 5. *Regulatory Agendas.*

(a) Each agency shall publish, in October and April of each year, an agenda of proposed regulations that the agency has issued or expects to issue, and currently effective rules that are under agency review pursuant to this Order. These agendas may be incorporated with the agendas published under 5 U.S.C. 602, and must contain at the minimum:

(1) A summary of the nature of each major rule being considered, the objectives and legal basis for the issuance of the rule, and an approximate schedule for completing action on any major rule for which the agency has issued a notice of proposed rulemaking;

(2) The name and telephone number of a knowledgeable agency official for each item on the agenda; and

(3) A list of existing regulations to be reviewed under the terms of this Order, and a brief discussion of each such regulation.

(b) The Director, subject to the direction of the Task Force, may, to the extent permitted by law:

(1) Require agencies to provide additional information in an agenda; and

(2) Require publication of the agenda in any form.

Sec. 6. *The Task Force and Office of Management and Budget.*

(a) To the extent permitted by law, the Director shall have authority, subject to the direction of the Task Force, to:

(1) Designate any proposed or existing rule as a major rule in accordance with Section 1(b) of this Order;

(2) Prepare and promulgate uniform standards for the identification of major rules and the development of Regulatory Impact Analyses;

(3) Require an agency to obtain and evaluate, in connection with a regulation, any additional relevant data from any appropriate source;

(4) Waive the requirements of Sections 3, 4, or 7 of this Order with respect to any proposed or existing major rule;

(5) Identify duplicative, overlapping and conflicting rules, existing or proposed, and existing or proposed rules that are inconsistent with the policies underlying statutes governing agencies other than the issuing agency or with the purposes of this Order, and, in each such case, require appropriate interagency consultation to minimize or eliminate such duplication, overlap, or conflict;

(6) Develop procedures for estimating the annual benefits and costs of agency regulations, on both an aggregate and economic or industrial sector basis, for purposes of compiling a regulatory budget;

(7) In consultation with interested agencies, prepare for consideration by the President recommendations for changes in the agencies' statutes; and

(8) Monitor agency compliance with the requirements of this Order and advise the President with respect to such compliance.

(b) The Director, subject to the direction of the Task Force, is authorized to establish procedures for the performance of all functions vested in the Director by this Order. The Director shall take appropriate steps to coordinate the implementation of the analysis, transmittal, review, and clearance provisions of this Order with the authorities and requirements provided for or imposed upon the Director and agencies under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, and the Paperwork Reduction Plan Act of 1980, 44 U.S.C. 3501 *et seq.*

Sec. 7. *Pending Regulations.*

(a) To the extent necessary to permit reconsideration in accordance with this Order, agencies shall, except as provided in Section 8 of this Order, suspend or postpone the effective dates of all major rules that they have promulgated in final form as of the date of this Order, but that have not yet become effective, excluding:

(1) Major rules that cannot legally be postponed or suspended;

(2) Major rules that, for good cause, ought to become effective as final rules without reconsideration. Agencies shall prepare, in accordance with Section 3 of this Order, a final Regulatory Impact Analysis for each major rule that they suspend or postpone.

(b) Agencies shall report to the Director no later than 15 days prior to the effective date of any rule that the agency has promulgated in final form as of the date of this Order, and that has not yet become effective, and that will not be reconsidered under subsection (a) of this Section:

(1) That the rule is excepted from reconsideration under subsection (a), including a brief statement of the legal or other reasons for that determination; or

(2) That the rule is not a major rule.

(c) The Director, subject to the direction of the Task Force, is authorized, to the extent permitted by law, to:

(1) Require reconsideration, in accordance with this Order, of any major rule that an agency has issued in final form as of the date of this Order and that has not become effective; and

(2) Designate a rule that an agency has issued in final form as of the date of this Order and that has not yet become effective as a major rule in accordance with Section 1(b) of this Order.

(d) Agencies may, in accordance with the Administrative Procedure Act and other applicable statutes, permit major rules that they have issued in final form as of the date of this Order, and that have not yet become effective, to take effect as interim rules while they are being reconsidered in accordance with this Order, *provided that,* agencies shall report to the Director, no later than 15 days before any such rule is proposed to take effect as an interim rule, that the rule should appropriately take effect as an interim rule while the rule is under reconsideration.

(e) Except as provided in Section 8 of this Order, agencies shall, to the extent permitted by law, refrain from promulgating as a final rule any proposed major rule that has been published or issued as of the date of this Order until a final Regulatory Impact Analysis, in accordance with Section 3 of this Order, has been prepared for the proposed major rule.

(f) Agencies shall report to the Director, no later than 30 days prior to promulgating as a final rule any proposed rule that the agency has published or issued as of the date of this Order and that has not been considered under the terms of this Order:

(1) That the rule cannot legally be considered in accordance with this Order, together with a brief explanation of the legal reasons barring such consideration; or

(2) That the rule is not a major rule, in which case the agency shall submit to the Director a copy of the proposed rule.

(g) The Director, subject to the direction of the Task Force, is authorized, to the extent permitted by law, to:

(1) Require consideration, in accordance with this Order, of any proposed major rule that the agency has published or issued as of the date of this Order; and

(2) Designate a proposed rule that an agency has published or issued as of the date of this Order, as a major rule in accordance with Section 1(b) of this Order.

(h) The Director shall be deemed to have determined that an agency's report to the Director under subsections (b), (d), or (f) of this Section is consistent with the purposes of this Order, unless the Director advises the agency to the contrary:

(1) Within 15 days of its report, in the case of any report under subsections (b) or (d); or

(2) Within 30 days of its report, in the case of any report under subsection (f).

(i) This Section does not supersede the President's Memorandum of January 29, 1981, entitled "Postponement of Pending Regulations", which shall remain in effect until March 30, 1981.

(j) In complying with this Section, agencies shall comply with all applicable provisions of the Administrative Procedure Act, and with any other procedural requirements made applicable to the agencies by other statutes.

Sec. 8. *Exemptions.*

(a) The procedures prescribed by this Order shall not apply to:

(1) Any regulation that responds to an emergency situation, *provided that,* any such regulation shall be reported to the Director as soon as it is practicable, the agency shall publish in the *Federal Register* a statement of the reasons why it is impracticable for the agency to follow the procedures of this Order with respect to such a rule, and the agency shall prepare and transmit as soon as is practicable a Regulatory Impact Analysis of any such major rule; and

(2) Any regulation for which consideration or reconsideration under the terms of this Order would conflict with deadlines imposed by statutes or by judicial order, *provided that,* any such regulation shall be reported to the Director together with a brief explanation of the conflict, the agency shall publish in the *Federal Register* a statement of the reasons why it is impracticable for the agency to follow the procedures of this Order with respect to such a rule, and the agency, in consultation with the Director, shall adhere to the requirements of this Order to the extent permitted by statutory or judicial deadlines.

(b) The Director, subject to the direction of the Task Force, may, in accordance with the purposes of this Order, exempt any class or category of regulations from any or all requirements of this Order.

Sec. 9. *Judicial Review.* This Order is intended only to improve the internal management of the Federal government, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person. The determinations made by agencies under Section 4 of this Order, and any Regulatory Impact Analyses for any rule, shall be made part of the whole record of agency action in connection with the rule.

Sec. 10. *Revocations.* Executive Orders No. 12044, as amended, and No. 12174 are revoked.

RONALD REAGAN

THE WHITE HOUSE
February 17, 1981

APPENDIX C

Executive Order No. 12,498
3 C.F.R. 323 (1985)

REGULATORY PLANNING PROCESS

By the authority vested in me as President by the Constitution and laws of the United States of America, and in order to create a coordinated process for developing on an annual basis the Administration's Regulatory Program, establish Administration regulatory priorities, increase the accountability of agency heads for the regulatory actions of their agencies, provide for Presidential oversight of the regulatory process, reduce the burdens of existing and future regulations, minimize duplication and conflict of regulations, and enhance public and Congressional understanding of the Administration's regulatory objectives, it is hereby ordered as follows:

Section 1. *General Requirements.* (a) There is hereby established a regulatory planning process by which the Administration will develop and publish a Regulatory Program for each year. To implement this process, each Executive agency subject to Executive Order No. 12291 shall submit to the Director of the Office of Management and Budget (OMB) each year, starting in 1985, a statement of its regulatory policies, goals, and objectives for the coming year and information concerning all significant regulatory actions under way or planned; however, the Director may exempt from this order such agencies or activities as the Director may deem appropriate in order to achieve the effective implementation of this order.

(b) The head of each Executive agency subject to this Order shall ensure that all regulatory actions are consistent with the goals of the agency and of the Administration, and will be appropriately implemented.

(c) This program is intended to complement the existing regulatory planning and review procedures of agencies and the Executive branch, including the procedures established by Executive Order No. 12291.

(d) To assure consistency with the goals of the Administration, the head of each agency subject to this Order shall adhere to the regulatory principles stated in Section 2 of Executive Order No. 12291, including those elaborated by the regulatory policy guidelines set forth in the August 11, 1983, Report of the Presidential Task Force on Regulatory Relief, "Reagan Administration Regulatory Achievements."

Sec. 2. *Agency Submission of Draft Regulatory Program.* (a) The head of each agency shall submit to the Director an overview of the agency's regulatory policies, goals, and objectives for the program year and such information concerning all significant regulatory actions of the agency, planned or under way, including actions taken to consider whether to initiate rulemaking; requests for public comment; and the development of documents that may influence, anticipate, or lead to the commencement of rulemaking proceedings at a later date, as the Director deems necessary to develop the Administration's Regulatory Program. This submission shall constitute the agency's draft regulatory program. The draft regulatory program shall be submitted to the Director each year, on a date to be specified by the Director, and shall cover the period from April 1 through March 31 of the following year.

(b) The overview portion of the agency's submission should discuss the agency's broad regulatory purposes, explain how they are consistent with the Administration's regulatory principles, and include a discussion of the significant regulatory actions, as defined by the Director, that it will take. The overview should specifically discuss the significant regulatory actions of the agency to revise or rescind existing rules.

(c) Each agency head shall categorize and describe the regulatory actions described in subsection (a) in such format as the Director shall specify and provide such additional information as the Director may request; however, the Director shall, by Bulletin or Circular, exempt from the requirements of this order any class or category of regulatory action that the Director determines is not necessary to review in order to achieve the effective implementation of the program.

Sec. 3. *Review, Compilation, and Publication of the Administration's Regulatory Program.* (a) In reviewing each agency's draft regulatory program, the Director shall (i) consider the consistency of the draft regulatory program with the Administration's policies and priorities and the draft regulatory programs submitted by other agencies; and (ii) identify such further regulatory or deregulatory actions as may, in his view, be necessary in order to achieve such consistency. In the event of disagreement over the content of the agency's draft regulatory program, the agency head or the Director may raise issues for further review by the President or by such appropriate Cabinet Council or other forum as the President may designate.

(b) Following the conclusion of the review process established by subsection (a), each agency head shall submit to the Director, by a date to be specified by the Director, the agency's final regulatory plan for compilation and publication as the Administration's Regulatory Program for that year. The Director shall circulate a draft of the Administration's Regulatory Program for agency comment, review, and interagency consideration, if necessary, before publication.

(c) After development of the Administration's Regulatory Program for the year, if the agency head proposes to take a regulatory action subject to the provisions of Section 2 and not previously submitted for review under this process, or if the agency head proposes to take a regulatory action that is materially different from the action described in the agency's final regulatory program, the agency head shall immediately advise the Director and submit the action to the Director for review in such format as the Director may specify. Except in the case of emergency situations, as defined by the Director, or statutory or judicial deadlines, the agency head shall refrain from taking the proposed regulatory action until the review of this submission by the Director is completed. As to those regulatory actions not also subject to Executive Order No. 12291, the Director shall be deemed to have concluded that the proposal is consistent with the purposes of this Order, unless he notifies the agency head to the contrary within 10 days of its submission. As to those regulatory actions subject to Executive Order No. 12291, the Director's review shall be governed by the provisions of Section 3(e) of that Order.

(d) Absent unusual circumstances, such as new statutory or judicial requirements or unanticipated emergency situations, the Director may, to the extent permitted by law, return for reconsideration any rule submitted for review under Executive Order No. 12291 that would be subject to Section 2 but was not included in the agency's final Regulatory Program for that year; or any other significant regulatory action that is materially different from those described in the Administration's Regulatory Program for that year.

Sec. 4. *Office of Management and Budget.* The Director of the Office of Management and Budget is authorized, to the extent permitted by law, to take such actions as may be necessary to carry out the provisions of this Order.

Sec. 5. *Judicial Review.* This Order is intended only to improve the internal management of the Federal government, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person.

RONALD REAGAN

THE WHITE HOUSE
January 4, 1985

APPENDIX D

OMB Memoranda Concerning Review Under Executive Order Nos. 12,291 and 12,498

Memorandum for the Heads of Departments and Agencies Subject to Executive Order Nos. 12,291 and 12,498

(June 13, 1986)

From the time the President signed Executive Order No. 12291 on February 17, 1981, OMB has worked with the Departments and Agencies to develop and implement various procedures concerning the review of draft rules by the Office of Information and Regulatory Affairs (OIRA). We have also developed trial procedures and supported legislative proposals concerning our reviews as we have gained experience with these Executive Orders. For example, last year we implemented on a pilot basis with the Environmental Protection Agency additional procedures concerning OIRA's communications with persons outside the Federal Government.

We have also supported an American Bar Association Resolution that endorsed the President's regulatory review efforts and recommended that more information concerning our reviews be made available to Congress and the public.

The purpose of this memorandum is to advise you of additional procedures that we have determined, as a matter of administrative discretion, to implement concerning our review of draft rules under Executive Order No. 12291 and to set forth our policy on disclosure of agency regulatory program drafts under Executive Order No. 12498.

Current Procedures

These new procedures supplement our current procedures. As you are aware, Executive Order No. 12291 establishes certain procedures; the Administrative Procedure Act sets forth procedural and substantive requirements that govern agency action; other statutes establish procedures; and OIRA has adopted its own internal rules concerning its review of draft rules under Executive Order No. 12291. Furthermore, Departments and Agencies usually have established rules or practices to implement their rulemaking activities.

Attached to this memorandum are copies of some of the relevant materials concerning our reviews and procedures. Several of the most important features of these current procedures are:

Reviews Under Executive Order No. 12291

- Rules must meet statutory requirements. Executive Order No. 12291 reviews cannot result in rules not authorized by law or rules that do not carry out statutory requirements.
- Rulemaking decisions are made by agency heads. Executive Order No. 12291 makes it clear that the rulemaking authority of the agency head is not displaced by the Order.
- Rules must be based on the agency record. Executive Order No. 12291 cannot cause rulemaking decisions that are not supported by the agency rulemaking record. The law requires that all agency decisions must be rationally based on information in the agency record.
- Requirements of Executive Order No. 12291 apply only to the extent permitted by law. If there is a conflict between the Executive Order or the President's regulatory principles in Executive Order No. 12291 and the law, the law governs.

Current OIRA Procedures

- Only the Administrator and Deputy Administrator within OIRA (or someone specifically designated by them) may communicate with someone who is not employed by the Federal Government on regulations submitted to OIRA for review under Executive Order No. 12291.
- Written materials received from anyone not employed by the Federal Government are made available in OIRA's public reading room for review by the public.

- OMB has advised persons who wish to send us information about regulatory proposals to *send information to the rulemaking agency*, with a copy to us so that the material may be made a part of the agency record.
- In general, OIRA provides *written reasons* to the agency whenever OIRA returns a regulation to an agency for further review because it is not consistent with the President's regulatory principles.
- OIRA issues *full reports* annually on the disposition of all rules reviewed under Exccutive Order No. 12291, including a list of all returned rules.

New Procedures

1. OIRA will make available, upon written request made to OIRA after publication of an ANPRM or NPRM in the *Federal Register*, copies of any draft of the ANPRM or NPRM submitted for OIRA's review under Executive Order No. 12291;
2. Similarly OIRA will make available, upon written request made to OIRA after publication of the final rule in the *Federal Register*, copies of any draft of the final rule submitted for OIRA's review under Executive Order No. 12291;
3. OIRA will make available, upon written request made to OIRA after the ANPRM, NPRM or the final rule is published in the *Federal Register*, all written correspondence concerning the draft submitted for OIRA's review under Executive Order No. 12291 that is exchanged between OIRA and the agency head. "Correspondence" means any documents exchanged between OIRA and the head of an agency.

These procedures are derived from provisions in S. 2433, as reported from the Senate Governmental Affairs Committee, with Administration support, in 1984. The Report on S. 2433 (No. 98–576, 98th Congress, 2d. Sess.) contains explanatory material as to how these provisions would have been interpreted had S. 2433 been enacted. We will be guided by that material in implementing these first three provisions.

4. OIRA will send EPA copies of all written material concerning EPA rules that OIRA receives from persons who are not employees of the Federal Government;
5. OIRA will advise EPA of all oral communications concerning EPA's rules, e.g., meetings, telephone calls, that OIRA (i.e. the Administrator and Deputy Administrator) has with persons who are not employees of the Federal Government; and
6. OIRA will invite EPA to all scheduled meetings with such persons concerning EPA's rules.

In May 1985, we instituted with EPA on a trial basis other procedures to better conform our Executive Order No. 12291 review procedures to EPA's somewhat unique internal procedures and statutory provisions concerning rulemaking. (See attached letter dated May 30, 1985, Attachment D.) These procedures are practical, and EPA believes that they are useful. This Memorandum revises those procedures with EPA and makes them a part of OIRA's current procedures.

(Note: These procedures do not apply to information collection requests under the Paperwork Reduction Act of 1980, even if such requests are a part of a proposed agency rule. Other procedures apply to such matters, see 5 CFR Part 1320.)

7. OIRA will apply these procedures (#4 through #6) to any other Department or Agency that is subject to Executive Order No. 12291 if that agency elects to institute these procedures, or any part of them.

Procedures #4 through #6 presently apply only to EPA. Although patterned upon EPA's statutory and internal procedures, nonetheless, OIRA is prepared to extend these procedures to other agencies if the head of the agency so requests. A current list of agencies that have requested coverage will be maintained in the public reading room.

In addition,

8. OIRA will make available upon written request to OIRA made after the Regulatory Program is published, any agency draft submission sent to OIRA under Executive Order No. 12498. A copy will be available in the public reading room;

9. OIRA will continue to publish a complete annual accounting of Executive Order No. 12291 activities;
10. OIRA will make available upon written request to OIRA made after the end of a calendar month a list of all draft ANPRMs, NPRMs and draft final rules for which OIRA has completed review under Executive Order No. 12291 during the preceding month (and the length of our review for each); and
11. OIRA will place in its public reading room: all written material received from persons outside the Federal Government concerning agency rules; a list of all meetings with persons outside the Federal Government pertaining to rules of an agency if that agency elects to participate in procedure #6; and a list of all other communications with persons outside the Federal Government pertaining to rules of any agency if that agency elects to participate in procedure #5.

Effective Date of New Procedures

The effective date of these new procedures is June 13, 1986, as explained below.

For purposes of new procedures #1 through #3, OIRA will make available in accordance with the conditions of those procedures, all drafts of the rule (and written correspondence referred to in procedure #3) if the review under Executive Order No. 12291 began on or after June 13, 1986, or was under review on that date. OIRA reviews of draft ANPRMs, NPRMs, and final rules will be separate actions for purposes of disclosure. For example, copies of a draft NPRM under procedure #1 will be available in accordance with the conditions of procedure #1 after publication of the NPRM, if it was pending on or submitted after June 13, 1986, for review under Executive Order No. 12291. Disclosure of the draft NPRM would not be delayed until publication of a final rule. The reviews are distinct events for disclosure purposes. Similarly, if a review under Executive Order No. 12291 of a draft NPRM was completed prior to June 13, 1986, it would not be covered by these new procedures. Drafts of the final rule would be subject to procedure #2 if the final rule was pending on or submitted after June 13, 1986.

For purposes of procedures #4 through #6, the effective date will be the date of receipt of the request by the head of an agency to have these procedures apply. They apply as of June 13, 1986, for EPA. (Trial procedures with EPA have been effective since May 30, 1985.)

Procedure #8 will apply to drafts of the agency submissions for the *1986 Regulatory Program* and thereafter. The annual accounting referenced in procedure #9 is an appendix to the annual *Regulatory Program*. The lists referred to in procedures #10 and #11 will be available in OIRA's public reading room and upon written request on the 10th day of the month following the month for which the list is made. The first list will be available August 10, 1986. All written material pertaining to rules subject to Executive Order No. 12291 review received from persons not employed by the Federal Government as described in procedure #11 will be available within 3 to 5 days after receipt by OIRA.

These new procedures and OIRA's existing procedures are intended only to improve the internal management of the Federal Government, and are not intended to create any right or benefit, substantive or procedural, enforceable at law or in equity by a party against the United States, its agencies, its officers, or any person.

WENDY L. GRAMM
Administrator,
Office of Information
and Regulatory Affairs

Attachments:

A—Department of Justice/OLC Opinion dtd 2/13/81
B—Executive Order No. 12291 (see Appendix I)
C—Executive Order No. 12498 (see Appendix II)
D—OIRA Procedures #3

Without attachments except D.

Appendix D

Memorandum for OIRA Staff Subject: OIRA Procedures # 3 (May 30, 1985)

The purpose of this memorandum is to remind you of the policies of the Office of Information and Regulatory Affairs under the Paperwork Reduction Act of 1980, Executive Order No. 12291, and Executive Order No. 12498, with respect to:

- records maintenance;
- public access to records; and
- meetings with the public.

These policies are intended to ensure that our responsibilities are discharged as efficiently and openly as practicable, consistent with both the law and the need for confidential communications between the President and his executive officers. Because OIRA's role in implementing the Paperwork Reduction Act is very different from its role in implementing Executive Order No. 12291 and Executive Order No. 12498, different procedures are necessary for our actions under each of these three programs. The differences derive primarily from the different authorities involved. The rules for Executive Order No. 12291 reviews will be applied to the Executive Order No. 12498 process to the extent they are relevant in that context.

BACKGROUND

OIRA's Role Under the Paperwork Reduction Act. In summary, the Paperwork Reduction Act requires OMB to review and approve or disapprove agency requests for information from the public. In this regard, the Paperwork Reduction Act essentially recodified the clearance authority that was originally assigned to OMB (actually the old Bureau of the Budget) by the Federal Reports Act of 1942.

OMB is responsible for determining whether agency information collection requirements meet the standards of the Act. Reviews under the Act determine whether the proposed information collection request is necessary for the proper performance of agency functions, including whether the information has "practical utility," whether it is too burdensome on respondents, and whether there is a need for the information. As a result, our actions may have legal, judicially reviewable consequences and must be based upon a complete record. The Act and our implementing rule specify the procedures that OIRA must follow. The bottom line is that we are responsible for ensuring that the record is complete and constitutes a justifiable basis for our decision, and that we adhere to the required procedures in developing the record and making our decision.

OIRA's Role Under E.O. 12291 and E.O. 12498. In contrast, our review under Executive Orders No. 12291 and No. 12498 derives from the President's constitutional authority over, and responsibility for actions taken by, his executive officers in carrying out the law. He has delegated his authority to review regulations to the Director of OMB. Thus, we conduct our reviews on behalf of the Director and the President.

In conducting an Executive Order review, OMB does not make final regulatory decisions—those are assigned by law to the heads of the respective agencies and must in all cases remain the regulatory agency's responsibility. The decision is made by the regulatory agency and the agency is accountable for both the adequacy of the record of its rulemaking and for justifying the substantive validity of the decision under the applicable statutes. We review the draft regulations of departments and agencies and advise whether the draft rules and their analysis meet the President's regulatory principles, as set forth in Executive Orders No. 12291 (Section 2) and No. 12498 (Section 1). As the Executive Orders note, our review is not intended to provide any third party with any procedural or substantive right concerning the regulations.

Since some regulations contain collections of information from the public, they are subject to our review and approval under the Paperwork Reduction Act as well as under Executive Order No. 12291.

Appendix D

THE DECISIONMAKING RECORD

The law generally requires that agencies must compile a record of materials that justify their rulemaking actions and that will serve as a basis for judicial review. The regulatory agency is also required under the Administrative Procedure Act to provide a concise general explanation for any regulations adopted by informal rulemaking and to explain, for example, significant substantive differences between an NPRM and a final rule, including new facts or data that the agency has relied upon.

For most rulemakings the law requires only that public comments on a proposed rule and certain underlying scientific and empirical data be included with a text of the notice of proposed rulemaking and a final rule in the rulemaking record. The agency may, and usually does, include in a preamble to a rule other material in the record that is significant and relevant to the rulemaking. But the rule must be based upon and justified by the whole rulemaking record. Factual material that is not in the rulemaking record may not be used as a basis for supporting a rule.

For paperwork reviews, OIRA is the decisionmaking agency; *we* open and maintain that record. Our decision to approve or disapprove is based upon this record and must be justified by it. The record we compile is the material that may be reviewed as the law provides by the courts.

For reviews of regulations under Executive Orders No. 12291 and No. 12498, the agency is the decisionmaker; for judicial review, its rulemaking file, not factual material available to us, is the relevant material. In accordance with the Director's Memorandum of June 11, 1981 (attached), we make available materials we receive from the public to the regulatory agency so it may consider such material and include it in its records if it chooses to do so.

When we conduct reviews and give advice under the Executive Orders, we and the agencies treat our discussions in the same way we handle such consultation on other subjects—they are not generally disclosed. We will, however, make available upon request to the public all written information that we receive from any member of the public that we consider in our review, our final recommendation letter (if any) to the agency under E.O. 12291, and, of course, any material we submit for inclusion in an agency rulemaking record.

The following additional policies should be used as guidance in implementing our responsibilities under the Paperwork Reduction Act of 1980 and Executive Orders No. 12291 and No. 12498.

RECORDS MAINTENANCE

Each OIRA supervisor is responsible for ensuring that the relevant documents are placed in the proper files on matters under their supervision.

Any supervisor (including the Administrator and Deputy Administrator) who receives written comments directly from a member of the public will promptly send a copy of the comments to the appropriate Desk Officer.

Any comments that would otherwise be included in the public record but for which the commentor proposes to limit public access should not be accepted without the approval of the Deputy Administrator. Jim MacRae is responsible for periodic review and disposition of all files for the purpose of retention, storage, or destruction, in accordance with the policies set forth below. Except in unusual circumstances, all documents that are not required by law to be retained should be disposed of when the documents that are required to be retained are transferred to the Federal Records Center.

- *Paperwork Reduction Act of 1980*
  - Because the written materials in our dockets are the documentary basis for our paperwork decisions and also constitute a basis for the public to review and comment to us on the proposed agency action, paperwork clearance dockets must be kept accurate, timely, and complete. To that end, Desk Officers should place in the docket, promptly after its receipt at OMB, any material that should be in the record.

- — The record should include the following material:
  - – Agency proposal and any revisions;
  - – OMB worksheet;
  - – All written comments from the public and other government agencies;
  - – Evidence of final OMB action.
- — After final action (approval or disapproval), the record should be retained in the reading room for at least 6 months. At least twice a year the Reports Management Staff will review the files and send to the Federal Records Center all records for which final action has been completed for at least six months. The records will be classified as "temporary" for the Federal Records Center.

- *Executive Order No. 12291*
  - — Because the head of the regulatory agency, not OMB, is the decisionmaker on all rulemaking issues that come to us under E.O. 12291, we will routinely make available to the appropriate regulatory agency copies of all written materials that we receive from members of the public during the rulemaking proceeding and that are relevant to a particular informal rulemaking.
  - — The Desk Officer should also send to the public reading file within three days after receipt a copy of any such comments received from members of the public.
  - — These Desk Officer should send a copy of the final OMB written recommendation to the agency (if any) to the public reading file within three days after transmittal to the agency.
  - — The following material will not be made public, but, in addition to the final written OMB recommendations/views to the agency (if any), will be retained as part of the regulatory files:
    - – draft and proposed agency materials;
    - – OMB worksheets; and
    - – internal OMB and interagency documents as described by 5 U.S.C. 552(b)(5).

- After completion of the OIRA review, the regulatory files should be retained for at least six months. At least twice a year, the Reports Management staff, assisted by the other Branches, will review the files and segregate all files for which the reviews have been completed for at least six months. All files of rules that were "consistent, with no change" will be sent to the Federal Records Center. All other files will be retained within the NEOB for one year, then sent to the Federal Records Center. All files sent to the Federal Records Center will be classified as "temporary."

PUBLIC ACCESS TO OUR DOCKETS AND RECORDS

FOIA requests should be handled in accordance with OMB FOIA procedures. In addition, we have customarily made our paperwork dockets and written information from the public available for inspection.

Notwithstanding the increased Secret Service security precautions in the New Executive Office Building, we must continue to make access to our public records as simple as possible. All clearances should be arranged through Jim MacRae's office, ext. 6880.

To avoid confusion and misunderstanding, visitors should be told at the time clearance is sought that their clearance is limited to the public reading room. If the individual who has been cleared does not arrive at the reading room shortly after their scheduled clearance time, Jim MacRae should be notified. Jim will alert the Secret Service, which will take appropriate action. We cannot permit individuals who are cleared into the building for the reading room to roam through the building.

- *Paperwork Reduction Act of 1980*
  - Current and recent records of paperwork clearance actions will be maintained in such a way as to be readily accessible to members of the public (with exceptions as provided in 5 CFR 1320.18). These files, which are the complete and official record for clearance purposes, will be kept in NEOB 3201, the reading

room. They will be accessible to the public during normal business hours—9:00 am–5:30 pm.

- *Executive Order No. 12291 and No. 12498*
  - — We will maintain two types of documents in our public files relating to regulatory reviews—all comments received from any member of the public, and all our final recommendation letters to agencies under Executive Order No. 12291. These files will also be accessible to the public in the reading room during normal business hours.

MEETING WITH MEMBERS OF THE PUBLIC (including telephone contacts)

- *Paperwork Reduction Act of 1980*
  - — Any Desk Officer or supervisor may meet with members of the public to discuss and receive data and facts that are relevant to a paperwork clearance decision.
  - — Consistent with the policies of this memorandum and available time, OIRA staff must be equally accessible to all members of the public.
  - — In making our paperwork decision, we will consider only information that we receive *in writing*. The OIRA staff should make this policy clear during any conversation with members of the public, and should advise them to submit their comments in writing to *both* OMB and the agency concerned.
  - — OIRA staff may provide the public with information regarding the status of our paperwork decisionmaking process and the material and factual basis of our review, but should refrain from discussing their views of the issues or speculating on the outcome of the review.
  - — If an information collection requirement is contained in a proposed rule, any discussion with members of the public must be limited exclusively to the information collection request.
  - — Other procedures concerning paperwork reviews are set forth in 5 CFR 1320 and the Act itself.

- *Executive Orders No. 12291 and No. 12498*
  - Inquires from persons outside of the Executive branch about regulatory matters under Executive Orders No. 12291 and No. 12498 shall be referred to the Deputy Administrator's Office or the appropriate agency.
  - Consistent with the policies of this memorandum and available time the Administrator and Deputy Administrator will be accessible to all members of the public.
  - No one within OIRA except the Administrator or Deputy Administrator will meet or talk with members of the public on Executive Orders No. 12291 and No. 12498 matters, unless specifically authorized by the Administrator or Deputy Administrator.
  - Members of the public should be advised to submit their comments in writing to the appropriate agency if they wish to submit them to OMB, as provided in the Director's letter of June 11, 1981. They should also be advised that any materials submitted to us will be made part of the public file and made available to the appropriate agency.

ROBERT P. BEDELL
Deputy Administrator
Office of Information
and Regulatory Affairs

Appendix D

Letter Concerning OIRA Review of EPA Rulemaking (May 30, 1985)

MR. A. JAMES BARNES
Deputy Administrator
Environmental Protection Agency

In recent discussions, you have asked us to review our present practices to ensure that factual information pertaining to EPA's rulemaking activities that is made available to us by members of the public is also made available to EPA in a timely manner.

We have reviewed our procedures and we believe that our general policies and practices under Executive Order No. 12291 are sound. However, in response to your request, we would propose certain additional procedures, beyond our existing policies and practices, which, if they are acceptable to you, we would be willing to undertake on an experimental basis.

Background

Our existing procedures implement guidance provided to us by the Attorney General in an opinion of April 24, 1981, entitled "Contacts between OMB and Executive Branch Agencies Pursuant to Executive Order 12291." It complements an earlier analysis by the Attorney General of the legal basis of the Executive Order (Memorandum re: Proposed Executive Order entitled "Federal Regulation," dated February 13, 1981). Both opinions of the Attorney General are enclosed (Tabs A and B).

The earliest of these two opinions of the Attorney General concluded that Executive Order No. 12291, which established the regulatory review process administered by the Office of Information and Regulatory Affairs was a lawful exercise of the President's Constitutional authority—

> "to 'supervise and guide' Executive Officers in 'their construction of the statutes under which they act in order to secure that unitary and uniform execution of the laws which Article II of the Constitution evidently contemplated in vesting general executive power in the President alone' *Myers* v. *United States,* 272 U.S. 52, 135 (1926)."

The second opinion of the Attorney General of April 24, 1981, concluded, in part that:

- The Office of Information and Regulatory Affairs, to which the authority of the Director of OMB under Executive Order No. 12291 has been delegated, "may freely contact agencies regarding the substance of proposed regulations, and may do so by way of telephone calls, meetings, or other forms of communication unavailable to members of the public."
- "[D]isclosure obligations, if any, lie with the rulemaking agency and not with [OIRA]."
- "[OIRA] is therefore under no legal disability with respect to contact with rulemaking agencies. At most, [OIRA] could adopt procedures as a matter of policy to assist the agencies in complying with our recommendation or with rules fashioned by the agencies themselves" (p.4).

This opinion, written before the seminal decision of the United States Court of Appeals for the District of Columbia Circuit in *Sierra Club* v. *Costle*, 657 F.2d 298 (1981), concluded that the judicial decisions issued until that time were "confused" as to whether an agency must include in its rulemaking record for judicial review factual information received by the agency from officials of the Executive Office of the President (EOP). The Attorney General therefore recommended that agencies include such factual information in their records in order to avoid the possibility of judicial reversal. The Attorney General did not, however, require or recommend inclusion of communications under the Executive Order that form part of the agency's deliberative process, i.e., legal and policy arguments, analyses of the facts, and factual data that cannot reasonably be segregated from deliberative material.

To implement the recommendations of the Attorney General, OMB Director David A. Stockman issued a Memorandum for the Heads of Executive Departments and Agencies on June 11, 1981, entitled "Certain Communications Pursuant to Executive Order

No. 12291, 'Federal Regulation' " (Tab C). That Memorandum emphasized "that the primary forum for receiving factual communications regarding proposed rules is the agency issuing the proposal, not the Task Force or OMB."

This emphasis on the agency as the forum for receiving factual communications merely reflects, of course, the fact that the Executive Order does not divest an agency head of authority provided by law or the legal requirement that agency rules must be based upon the rulemaking record.

Since these procedures were implemented, the court's decision in *Sierra Club* has clearly established the propriety of contacts between EOP officials and agencies concerning rulemaking—indeed, it has demonstrated their importance for proper policy guidance of this critical aspect of government activity—and demonstrated that the procedures recommended by the Attorney General and implemented by the Director's Memorandum go well beyond what is required by law.

Written Materials from Persons Outside the Executive Branch

The Director's Memorandum provided that:

- Factual materials that are sent to the Presidential Task Force on Regulatory Relief or OIRA regarding proposed regulations should indicate that they have also been sent to the relevant agency. Pursuant to this policy, the Memorandum noted that the Task Force and OIRA would regularly advise those members of the public with whom they communicated that relevant factual materials submitted to them should also be sent to the agency for inclusion in the rulemaking record.
- Accordingly, agencies receiving such materials from the public should take care to see that they are placed in the record.
- On occasion, the Task Force staff and OIRA would receive or develop factual material that they believe should be considered by an

> agency during a particular informal rulemaking. The Memorandum provided that, in accordance with advice provided by the Department of Justice, such material, when submitted to an agency for its consideration, would be identified as material appropriate for inclusion in the record of the agency rulemaking.

To further implement the recommendations of the Attorney General, OIRA established additional procedures, as a matter of policy, beyond the requirements of law and the recommendations of the Attorney General. Thus, we have uniformly and consistently made available to Members of Congress, the agencies, and the public copies of documents concerning an agency rulemaking that we have received from perons who are not officials or employees of the executive branch. We also strive to maintain copies of all such documents in our materials that are available for public review.

In addition to such materials being lodged in our public files and copies being made available upon request, you have asked whether copies of such documents that pertain to EPA rules could be routinely sent to EPA to help ensure that such materials are included, if appropriate, in EPA rulemaking dockets. In order to accommodate you, we will send to the General Counsel of EPA copies of all such documents that we receive from persons outside the executive branch. We will seek to provide these copies within five working days of their receipt in OIRA.

Non-written Communications with Persons Outside the Executive Branch

As you know, our practice with regard to non-written communications with persons outside the Federal Government, e.g., telephone calls and meetings, is to constrain communications that pertain to proposed agency rules. Only the Administrator and I (or OIRA employees specifically authorized by us in unusual circumstances) are authorized to communicate with persons outside the Federal Government on the substance (as opposed to the status) of rules that are subject to review under Executive Order No. 12291.

These restrictions also apply to our review of rulemaking activities pursuant to Executive Order No. 12498. These restrictions do not apply to the other functions and activities of OIRA, such as our review of information collection requests under the Paperwork Reduction Act of 1980, even if an information collection request is contained in a proposed rule. In this latter circumstance, different procedures apply. See 5 CFR Part 1320 (Tab D) and OIRA Procedures Memorandum #3 (Tab E). The limitations noted above do, however, apply to the parts of a rule that do not contain an information collection request.

Obviously, senior officials in OIRA must be able to communicate freely with members of the public and persons within the Federal Government, just as the senior officials in EPA do.[11] We have, however, limited such communications essentially to the Administrator and Deputy Administrator. Furthermore, even Doug and I usually do not communicate with persons outside the Federal Government on proposed agency rules while they are under review pursuant to Executive Order No. 12291.

Notwithstanding these procedures applicable to all rules subject to the Order, you have asked whether specific additional procedures could be fashioned to apprise EPA of factual information that becomes available to us as a result of non-written communications with persons outside the Federal Government and that pertain to proposed EPA rules. Before describing what we believe is appropriate, it is useful first to deal with an approach we have rejected and the reasons why.

"Logging"

Although you have not suggested it, we believe that a general "logging" program or some variant thereof, particularly between and within executive agencies and entities, would not be an acceptable solution and would, as a general matter, be bad policy. The Attorney General's opinion of April 24, 1981, confirms this at pages 7–9 (Tab A). This view is also reflected in *Sierra Club v. Costle*, 657 F.2d 298, 404–408 (1981); prior congressional consideration of the issue (see pp. 3–4, Tab A); and, EPA's own stated position on the matter (Tab F).

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[11] As the court stated in *Sierra Club v. Costle*, "Under our system of government, the very legitimacy of general policymaking performed by unelected administrators depends in no small part upon the openness, accessibility and amenability of these officials to the needs and ideas of the public from whom their ultimate authority derives, and upon whom their commands must fall. . . . Furthermore, the importance to effective regulation of continuing contact with a regulated industry, other affected groups, and the public cannot be underestimated. Informal contacts may enable the agency to win needed support for its program, reduce future enforcement requirements by helping those regulated to anticipate and shape their plans for the future, and spur the provision of information which the agency needs." 657 F.2d 298, 400-1 (1981).

In a nutshell, here is why we think a general "logging" system is a bad idea.

- It is unnecessary. There would be no adverse legal consequence even if we were to have information that is not in the agency record. An agency rule must be based on material in the record. Since EPA cannot rely on information it does not have to support a rule, see 657 F.2d 401, factual information that might be available to us from persons outside the Federal Government, that is not also made available to EPA, is not pertinent. Furthermore, an agency has no use for who-talked-to-whom entries.
- Imposition of a logging requirement would improperly interfere with the communication of policy views within the executive branch and the deliberative process itself. The court in *Sierra Club* rejected this approach. This was also a basis for Congress' rejection of the proposal to apply "ex parte" requirements to informal rulemaking. See pages 3 and 4 of Tab A, particularly footnotes 5–8.
- It is contrary to the "legislative model" of informal rulemaking[12] adopted by the Congress.
- It would divert attention from whether the agency's decision is a good one—the substantive issue—to how the agency made the decision.
- It would establish a paperwork blizzard if all participants in all discussions were required to "log" all communications on the thousands of rules considered every year. This would be

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[12] Where agency action resembles judicial action, where it involves formal rulemaking, adjudication, or quasi-adjudication among "conflicting private claims to a valuable privilege," the insulation of the decisionmaker from *ex parte* contacts is justified by basic notions of due process. But where agency action involves informal rulemaking of a policymaking sort, the concept of *ex parte* contacts is of more questionable utility.

nothing short of a bureaucratic nightmare to administer.

- A "logging requirement" would be impossible to "define." When would it begin? Who would it cover? When would it end? What would it consist of? There are neither practical not principled answers to these questions.
- Such a procedure would logically require the agency to log all of its internal deliberative discussions also—a practical impossibility.

Additional Procedures

Nonetheless, in order to increase the amount of factual information that is available to EPA for its rulemaking decisions, and to respond to your request, we propose the following procedure which, if acceptable to you, we would try for a period of time and then reassess with you.

Whenever the Administrator or I have a meeting or a telephone call with a person outside of the executive branch concerning a proposed EPA rule subject to Executive Order No. 12291, and that meeting or telephone call provides factual information that we are not confident has also been provided to EPA, either the Administrator or I will call the General Counsel of EPA and advise him of the communication and of the relevant factual information. EPA can then do whatever it deems appropriate with regard to the information reported to the General Counsel. Furthermore, with respect to scheduled meeting, if any, we will try for a period of time and for a few rulemakings to provide an opportunity for senior officials of EPA to attend and participate, if they choose to do so. After some experience, we will reassess this procedure, as well.

Please let me know if you believe that we should initiate these procedures.

Robert P. Bedell
Deputy Administrator
Office of Information and
Regulatory Affairs

Enclosures

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

RECOMMENDATIONS AND STATEMENTS RELATING TO RULEMAKING

1. Recommendation 69-8: "Elimination of Certain Exemptions from the APA Rulemaking Requirements," 1 C.F.R. § 305.69-8.2.

    Bonfield, *Public Participation in Federal Rulemaking Relating to Public Property, Loans, Grants, Benefits, or Contracts*, 118 U. Pa. L. Rev. 540 (1970); 1 ACUS Recommendations & Reports 306 (1971).

2. Recommendation 71-3: "Articulation of Agency Policies," 1 C.F.R. § 305.71-3.

    Clagett, *Informal Action - Adjudication - Rule Making: Some Recent Developments in Federal Administrative Law*, 1971 Duke L. J. 51.

3. Recommendation 71-6: "Public Participation in Administrative Hearings," 1 C.F.R. § 305.71-6.

    Cramton, *The Why, Where, and How of Broadened Public Participation in the Administrative Process*, 60 Geo. L. J. 525 (1972); 2 ACUS Recommendations & Reports 422 (1973).

    Gellhorn, *Public Participation in Administrative Proceedings*, 81 Yale L. J. 359 (1972); 2 ACUS Recommendations & Reports 376 (1973).

4. Recommendation 71-7: "Rulemaking on a Record by the Food and Drug Administration," 2 ACUS Recommendations & Reports 42 (1973).

    Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 Tex. L. Rev. 1132 (1972); 2 ACUS Recommendations & Reports 448 (1973).

5. Recommendation 72-5: "Procedures for the Adoption of Rules of General Applicability," 1 C.F.R. § 305.72-5.

    Hamilton, *Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in*

Administrative Rulemaking, 60 Calif. L. Rev. 1276 (1972); 2 ACUS Recommendations & Reports 834 (1973).

6. Recommendation 73-5: "Elimination of the 'Military or Foreign Affairs Function' Exemption from APA Rulemaking Requirements," 1 C.F.R. § 305.73-5.

   Bonfield, *"Military and Foreign Affairs Function" Rulemaking under the APA*, 71 Mich. L. Rev. 221 (1972); 3 ACUS Recommendations & Reports 226 (1975).

7. Recommendation 74-4: "Preenforcement Judicial Review of Rules of General Applicability," 1 C.F.R. § 305.74-4.

   Verkuil, *Judicial Review of Informal Rulemaking*, 60 Va. L. Rev. 185 (1974).

8. Recommendation 75-3: "The Choice of Forum for Judicial Review of Administrative Action," 1 C.F.R. § 305.75-3.

   Currie & Goodman, *Judicial Review of Federal Administrative Action: Quest for the Optimum Forum*, 75 Colum. L. Rev. 1 (1975); 4 ACUS Recommendations & Reports 197 (1979).

9. Recommendation 76-3: "Procedures in Addition to Notice and the Opportunity for Comment in Informal Rulemaking," 1 C.F.R. § 305.76-3.

   Williams, *"Hybrid Rulemaking" under the Administrative Procedure Act: A Legal and Empirical Analysis*, 42 U. Chi. L. Rev. 401 (1975); 4 ACUS Recommendations & Reports 499 (1979).

10. Recommendation 76-5: "Interpretive Rules of General Applicability and Statements of General Policy," 1 C.F.R. § 305.76-5.

    Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 Mich. L. Rev. 521 (1977); 4 ACUS Recommendations & Reports 615 (1979).

11. Recommendation 77-1: "Legislative Veto of Administrative Regulations," 4 ACUS Recommendations & Reports 63 (1979).

    Gellhorn & Bruff, *Congressional Control of Administrative Regulation: A Study of Legislative Vetoes*, 90 Harv. L. Rev. 1369 (1977); 4 ACUS Recommendations & Reports 679 (1979).

12. Recommendation 77-3: "Ex Parte Communications in Informal Rulemaking Proceedings," 1 C.F.R. § 305.77-3.

Nathanson, *Report to the Select Committee on Ex Parte Communications in Informal Rulemaking Proceedings*, 30 Admin. L. Rev. 377 (1978); 4 ACUS Recommendations & Reports 841 (1979).

13. Recommendation 78-3: "Time Limits on Agency Actions," 1 C.F.R. § 305.78-3.

Tomlinson, *Report on the Experience of Various Agencies with Statutory Time Limits Applicable to Licensing or Clearance Functions and to Rulemaking*, 1978 ACUS Recommendations & Reports 119.

14. Recommendation 78-4: "Federal Agency Interaction with Private Standard-Setting Organizations in Health and Safety Regulation," 1 C.F.R. § 305.78-4.

Hamilton, *Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety or Health*, 56 Tex. L. Rev. 1329 (1978); 1978 ACUS Recommendations & Reports 247.

15. Recommendation 79-1: "Hybrid Rulemaking Procedures of the Federal Trade Commission," 1979 ACUS Recommendations & Reports 3.

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16. Recommendation 79-4: "Public Disclosure Concerning the Use of Cost-Benefit and Similar Analyses in Regulation," 1 C.F.R. § 305.79-4.

Baram, *Regulation of Health, Safety and Environmental Quality and the Use of Cost-Benefit Analysis*, 8 Ecology L. Q. 473 (1980); 1979 ACUS Recommendations & Reports 377.

17. Recommendation 79-5: "Hybrid Rulemaking Procedures of the Federal Trade Commission - Administration of the Program to Reimburse Participants' Expenses," 1979 ACUS Recommendations & Reports 29.

> Boyer, *Funding Public Participants in Administrative Rulemaking: The Federal Trade Commission Experience*, 70 Geo. L. J. 51 (1981), 1979 ACUS Recommendations & Reports 437.

18. Recommendation 79-6: "Elimination of the Presumption of Validity of Agency Rules and Regulations in Judicial Review, as Exemplified by the Bumpers Amendment," 1979 ACUS Recommendations & Reports 33.

> Levin, *Judicial Review and the Bumpers Amendment*, Current Issues in Regulatory Reform 264, Washington, D.C., Federal Bar Association (M. L. Rosenberg and B. B. McGovern ed. 1980); 1979 ACUS Recommendations & Reports 565.

19. Recommendation 79-7: "Appropriate Restrictions on Participation by a Former Agency Official in Matters Involving the Agency," 1 C.F.R. § 305.79-7.

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21. Recommendation 80-4: "Decisional Officials' Participation in Rulemaking Proceedings," 1 C.F.R. § 305.80-4.

> Strauss, *Disqualification of Decisional Officials in Rulemaking*, 80 Colum. L. Rev. 990 (1980); 1980 ACUS Recommendations & Reports 375.

22. Recommendation 80-5: "Eliminating or Simplifying the 'Race to the Courthouse' in Appeals from Agency Action," 1980 ACUS Recommendations & Reports 25.

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23. Recommendation 80-6: "Intragovernmental Communications in Informal Rulemaking Proceedings," 1 C.F.R. § 305.80-6.

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> Luneburg, *Petitions for Rulemaking: Federal Agency Practice and Recommendations for Improvement*, 1988 Wis. L. Rev. 1 (1988); 1986 ACUS Recommendations & Reports 493.

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33. Recommendation 88-7: "Valuation of Human Life in Regulatory Decisionmaking," 1 C.F.R. § 305.88-7.

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35. Recommendation 89-5: "Achieving Judicial Acceptance of Agency Statutory Interpretations," 1 C.F.R. § 305.89-5.

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☆ U.S. GOVERNMENT PRINTING OFFICE: 1991-248-708/40182